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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE CORMEDIX INC. SECURITIES LITIGATION	Case No. 2:21-cv-14020 JXN CLW **CLASS ACTION**
THIS DOCUMENT RELATES TO: ALL CASES	THIRD AMENDED CONSOLIDATED CLASS ACTION COMPLAINT Honorable Julien Neals **JURY TRIAL DEMANDED**

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TABLE OF DEFINED TERMS

API	Active Pharmaceutical Ingredients
Board	CorMedix Inc.'s Board of Directors
CAPA	Corrective and preventative action
CEO	Chief Executive Officer
CFO	Chief Financial Officer
cGMP	Current Good Manufacturing Practice
Class	All persons and entities, other than Defendants, that purchased or otherwise acquired CorMedix securities between October 16, 2019 and August 8, 2022, both dates inclusive
Class Period	October 16, 2019 through August 8, 2022, both dates inclusive.
CLS	Catheter lock solution
CMC	Chemistry, Manufacturing and Controls
CMO	Contract Manufacturing Organization
Company	CorMedix Inc.
CorMedix	CorMedix Inc.
CRBSI	Catheter-related bloodstream infections
CRL	Complete Response Letter
Deenath	U.S. proprietary name for Neutrolin
Defendants	CorMedix, Khoso Baluch, Robert Cook, Phoebe Mounts, John L. Armstrong, Matthew David, and Joe Todisco
EVP	Executive Vice President
Exchange Act	Securities Exchange Act of 1934
FD&C Act	Food, Drug and Cosmetic Act
FDA	U.S. Food and Drug Administration
FE	Former Employee
Individual Defendants	Baluch, Cook, Mounts, Armstrong, David, and Todisco
Lead Plaintiff	John V. Levon
NASDAQ	NASDAQ Stock Market
NDA	New Drug Application
Neutrolin	Antibacterial and antifungal solution designed to prevent CRBSIs
NYSE	New York Stock Exchange
PAI	Pre-approval inspection

PDUFA	Prescription Drug User Fee Act
Plaintiff	Lead Plaintiff
ROVI	ROVI Contract Manufacturing, S.L
QIDP	Qualified Infectious Disease Product
SEC	U.S. Securities and Exchange Commission
SVP	Senior Vice President

Lead Plaintiff John V. Levon ("Plaintiff"), by and through his undersigned attorneys, on behalf of himself and all others similarly situated, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, but was not limited to, the review of defendants' public documents, conference calls and announcements made by defendants, U.S. Securities and Exchange Commission ("SEC") filings, wire and press releases published by and about CorMedix Inc. ("CorMedix" or the "Company"), analysts' reports and advisories about CorMedix, recently-released regulatory communications between CorMedix and the U.S. Food and Drug Administration ("FDA"), interviews with knowledgeable former CorMedix employees and affiliates, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support for the allegations set forth herein will become available after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons and entities, other than Defendants, that purchased or otherwise acquired CorMedix securities between October 16, 2019 and August 8, 2022, both dates inclusive ("Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities

Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. During the Class Period, Defendants focused on securing FDA approval for CorMedix's lead product candidate, Neutrolin® ("Neutrolin") (later renamed – and referred to herein as – DefenCath), a solution for catheter-related infections.

3. Drug sponsors seeking FDA approval of a new drug for U.S. sale, marketing, and commercial distribution must submit a New Drug Application (or "NDA"). The FDA has made clear that through the NDA process, drug sponsors must show that the methods used to manufacture the drug and the controls used to maintain its quality are adequate to preserve its identity, strength, quality and purity. In particular, CorMedix was required to maintain a demonstrably consistent manufacturing process for DefenCath, and to oversee and manage any affiliated third-party commercial manufacturing organizations ("CMOs").

4. In 2017, DefenCath selected a CMO for DefenCath, ROVI Contract Manufacturing, S.L., ("ROVI"), located in Spain.

5. In 2018, CorMedix commissioned an audit of ROVI which recommended that it not be used, as it would not be able to pass an FDA inspection. CorMedix did not disclose the existence of this audit or its conclusions, and inexplicably pushed ahead with ROVI as CMO.

6. Defendants further obscured the truth by claiming to investors that

Company knew what it was doing in regard to its commercial manufacturing met FDA standards. In August 2019, Defendant Jack L. Armstrong, the Company's Executive Vice President (EVP) of Technical Operations since 2017, specifically assured investors that:

> ***CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites. This should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it***. … And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved.[1]

7. Thus, on the first day of the Class Period, October 16, 2019, CorMedix seemed to have all the data, processes and controls – including the manufacturing information – needed to submit a successful NDA for Neutrolin when it issued a press release claiming that "***[t]he FDA was supportive of Neutrolin's proposed manufacturing program, including the active pharmaceutical ingredients ("API"), the container closure and testing***". On this announcement, CorMedix's stock price increased by over 9%.

8. On November 7, 2019, the FDA privately instructed CorMedix to identify all manufacturing facilities associated with DefenCath and to ensure those facilities be ready for inspection by the time the Company formally applied for FDA

[1] Emphasis added except where otherwise noted.

approval.

9. Then, during the first earnings call of the Class Period, on November 14, 2019, while reiterating that the FDA supported CorMedix's manufacturing efforts, Defendant Armstrong noted that that "FDA did request some additional data which we are working to complete." He did not, however, elaborate on the specific nature of the requested "additional data."

10. While hinting at a possible issue in CorMedix's CMC module for Neutrolin that concerned the FDA enough to request more information, Armstrong quickly reassured investors of the Company and its manufacturing team's proven "***breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance***," reiterating its five-year track record of successfully manufacturing and selling Neutrolin outside the U.S., and its success in completing "***technical transfer and validation of the manufacturing process***" which enabled "***the successful production of product at three different manufacturing sites***."

11. As the market absorbed these and other positive statements about how the Company's manufacturing was on track for a successful NDA submission, its stock jumped 24% over the next two trading days.

12. After the FDA accepted the Neutrolin NDA for rolling review in February 2020, CorMedix began its submission the next month, completing it in June 2020. At the same time, the FDA begun to substantively review the NDA and engaged

in ongoing dialogue with the Company to determine, *inter alia*, whether the facility that would be manufacturing, processing, packaging, or holding Neutrolin met FDA standards designed to assure its continued safety, quality, and purity.

13. By May 2020, the FDA had conditionally approved DefenCath™ ("DefenCath") as the U.S. proprietary name for Neutrolin. In the same month, the Company formed a wholly owned subsidiary in Spain, CorMedix Spain, S.L.U., apparently to better oversee and/or manage its CMO for its U.S. drug product as well as its API heparin manufacturer as the COVID-19 pandemic spread globally.

14. In the face of challenges caused by the pandemic, on July 8, 2020, Defendants highlighted to investors their ability to submit a complete NDA and portrayed the Company and its CMO as having successfully collected the information and/or data required to meet FDA standards: all that was left was approval. On this news, CorMedix's stock price increased 7%.

15. Throughout the rest of the Class Period, Defendants touted more milestones that maintained or increased the Company's stock price while regularly noting that the FDA "had not identified any potential review issues":

- 8/31/20: CorMedix announced that the FDA had accepted the DefenCath NDA for filing and granted it Priority Review with a Prescription Drug User Fee Act ("PDUFA") date of February 28, 2021.[2]

[2] Under Priority Review, the FDA reduces its review time from ten months to six. *See* U.S. FOOD & DRUG ADMIN., *Priority Review* (Jan. 4, 2018),

- 11/18/20: CorMedix announced that an advisory committee meeting for the DefenCath NDA was not needed.

16. Capitalizing on its stock price, CorMedix conducted a public offering on July 29, 2020, originally issued on November 27, 2020, and supplemented on August 12, 2021.

17. Based on well-established current Good Manufacturing Practice ("cGMP") standards and the Company's ongoing dialogue with the FDA, the Individual Defendants were ultimately responsible for ensuring processes were in place to assure the control of outsourced activities (*e.g.*, manufacturing) and quality of purchased substances (*e.g.*, heparin).

18. Unbeknownst to investors, however, Defendants submitted the DefenCath NDA without competently verifying its completeness or maintaining sufficient processes and controls to ensure contracting facilities had met and would continue to meet FDA standards for commercial readiness.

19. At the same time, Defendants raised funds by conducting public offerings of CorMedix shares, and improperly benefited from the inflated share price caused by Defendants' misstatements and/or omissions of material facts concerning the CMC information provided in the NDA and the capabilities of the Company's manufacturers.

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https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.

20. On February 26, 2021, the FDA issued a CRL (the "First CRL") to CorMedix explaining that the DefenCath NDA could not be (and would not be) approved until manufacturing issues at its CMO, ROVI, were fully remedied. As the FDA explained, "(1) the drug product manufacturing facility (ROVI Pharma Industrial Services S.A.) was found inadequate following a 704(a)(4) based review; and (2) inadequate in-process controls were proposed for … the drug product manufacturing process."[3]

21. Having been kept in the dark by Defendants, investors were shocked when, on March 1, 2021, CorMedix issued a press release announcing the First CRL instead of FDA approval. The Company detailed, *inter alia*, that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility" and the "FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications."[4]

22. On this news, CorMedix's stock price fell nearly 40% on March 1, 2021.

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[3] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/214520Orig1s000MultidisciplineR.pdf at 3.

[4] *CorMedix Receives Complete Response Letter from FDA for DefenCath™ Catheter Lock Solution*, GLOBENEWSWIRE (Mar. 1, 2021, 08:30 ET) ("3/1/21 Press Release"), https://www.globenewswire.com/en/news-release/2021/03/01/2184292/0/en/CorMedix-Receives-Complete-Response-Letter-From-FDA-for-DefenCath-Catheter-Lock-Solution.html.

As one industry analyst explained, the "CRL due to third party manufacturing issues … ***comes as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).

23. While conceding their knowledge of the FDA's request for more information from their CMO, Defendants assured industry analysts (and investors) that "the CMO manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards" and "the CMO is experienced in handling drug/device combos similar in scope to DefenCath."

24. And during the Company's first call with analysts and investors after the First CRL on March 9, 2021, Defendants downplayed the issues underlying the CRL, including that "one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the manufacturer of DEFENCATH" and that the additional requested manual extraction study and airflow visualization study would be "completed in the next several weeks." Based on these and other statements, industry analysts and investors believed that the "the manufacturing issues are straightforward and can be resolved within weeks."

25. That was not the case, however. As analysts and investors learned on April 14, 2021, CorMedix could not resubmit an NDA until the third quarter of 2021 ("3Q21") because it had to take additional steps for DefenCath's manufacturing

process to meet regulatory standards, including "[a]ddressing FDA's concerns regarding the qualification of the filling operation [that] may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath." On this news, CorMedix's stock price fell over 18%.

26. While disclosing that the Company's original proposed resolutions to the deficiencies underlying the First CRL were insufficient, Defendants assured investors that the Company was finally aligned with the FDA after "[k]ey representatives from both CorMedix and its CMO participated in a meeting…to address the deficiencies noted in the [First] CRL." As a result, industry analysts (and investors) were "confident that there [wa]s a clear resolution plan agreed upon with the FDA to address the manufacturing CRL" and "anticipate[d] NDA resubmission in the next few months by around 3Q21 followed by FDA decision on the need for a site visit sometime in late 3Q21 or 4Q21[.]"

27. But then, on May 13, 2021, CorMedix disclosed it could not resubmit its NDA until the fourth quarter of 2021 ("4Q21") because "additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA." On this news, CorMedix's stock price fell nearly 20%.

28. Defendants, however, continued to tout the Company and its CMO's ability to resolve the manufacturing deficiencies and resubmit its NDA by the end of the year:

- 5/13/21: "***[W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency***."
- 8/12/21: "***[W]e are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021. … [W]e have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified[.]***"

29. But investors learned on September 7, 2021 that not only had CorMedix "encountered delays at its third-party [CMO]," but that "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA is uncertain[.]" On this news, CorMedix's stock price fell over 27%.

30. Moreover, these delays in resolving the manufacturing deficiencies underlying the First CRL and resubmitting the DefenCath NDA indicated that CorMedix did not have the "right team" to resolve the deficiencies, as confirmed on October 4, 2021.

31. CorMedix again confirmed that it did not have the "right team" to resolve the manufacturing deficiencies identified by the FDA when on November 9, 2021, Defendant Mounts admitted that "we have engaged [a] team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection."

32. Defendants' assurances about manufacturing after the First CRL, and each subsequent delay, was intended to and did lead investors to believe that the Company had finally done what it needed to according to FDA standards when it

announced its resubmission of the DefenCath NDA on February 28, 2022, and the FDA's acceptance for review on March 28, 2022.

33. Unfortunately, CorMedix's shareholders had been misled yet again. On August 4, 2022, the Company received another CRL (the "Second CRL"). In summarizing the Second CRL, the FDA explained that "the status of the drug product manufacturing facility was ***again*** found unacceptable. In addition, the proposed commercial manufacturer of the heparin sodium drug substance … was also found unacceptable."[5]

34. In sharp contrast to CorMedix's six months of reassurances to the market, not only did unresolved manufacturing deficiencies persist at ROVI's facilities, but CorMedix had improperly attempted to resolve a customs hold-up involving its existing heparin supplier by adding another supplier without properly disclosing this new supplier to the FDA or ensuring that both suppliers used the same vial size.

35. After markets closed on August 8, 2022, CorMedix disclosed its receipt of a Second CRL "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA."[6] CorMedix further

[5] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/214520Orig1s000MultidisciplineR.pdf at 3.

[6] *CorMedix Inc. Announces Regulatory and Manufacturing Updates* GLOBENEWSWIRE, (Aug. 8, 2022) ("8/8/22 Press Release"),

admitted that the CMO it selected, ROVI, needed "an independent CGMP consultant to expedite the implementation of corrective actions."

36. Investors were stunned. CorMedix's stock price plummeted over 57% in response.

37. The adverse developments at issue here impacted the most central aspect, or the core, of CorMedix's business, operations, and revenue. Thus, the Company was particularly incentivized to take advantage of DefenCath's U.S. prospects. During the Class Period, Defendants' communications to the public almost exclusively concerned the DefenCath NDA, and they repeatedly emphasized the Company's expertise and progress in developing and commercializing DefenCath for U.S. marketing.

38. Moreover, while the Company was waiting for a decision from the FDA, it needed liquidity to stay afloat, and to raise capital at favorable terms, it needed to keep its stock price as high as possible.

39. As a result, the success of the DefenCath NDA was highly material to CorMedix's business during the Class Period. Indeed, it represented to investors that all its products besides DefenCath had an "immaterial" impact on its financial performance and business prospects. If CorMedix was not able to commercialize its main product in the U.S., it would have a material impact on the Company's profits

https://www.globenewswire.com/news-release/2022/08/08/2494270/0/en/CorMedix-Inc-Announces-Regulatory-and-Manufacturing-Updates.html.

and operations for the simple reason that DefenCath was, at least during the relevant time period, the Company's sole focus. Indeed, during the Class Period, CorMedix focused nearly all of its manufacturing and product marketing to support the commercialization of DefenCath.

40. In sum, throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business and operations. Specifically, they made material misstatements and/or failed to disclose material facts, including that: (i) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iii) the DefenCath NDA reflected those deficiencies; (iv) because of the foregoing deficiencies, the DefenCath NDA was at a substantial risk of being rejected by the FDA; (v) despite the First CRL, Defendants downplayed the true scope of the deficiencies identified with regards to, the manufacturing process set forth in the NDA, and the facility manufacturing DefenCath; (vi) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved"; (vii) upon

learning of new equipment at the CMO facility, Defendants failed to take necessary steps to ensure that the CMO's quality assurance protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards; (viii) as a result of deficient protocols, the CMO manufactured contaminated vials in July 2021, which delayed the Company's ability to obtain necessary validation data for resubmission of the DefenCath NDA; (ix) the CMO's facilities continued to be cGMP non-compliant, as the FDA's on-site inspection confirmed; (x) the FDA had observed manufacturing deficiencies at the Company's third-party facility supplying heparin, which warranted the issuance of a Form 483 on February 4, 2022, and added to the substantial risk of the FDA denying the DefenCath NDA for a second time; and (xi) as a result, the Company's public statements were materially false and misleading statements and/or omissions at all relevant times.

41. As a result of Defendants' misstatements and/or omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

42. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

43. This Court has jurisdiction over the subject matter of this action pursuant

to §27 of the Exchange Act, and 28 U.S.C. §1331.

44. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act, and 28 U.S.C. §1391(b). In this Judicial District is where CorMedix is headquartered, Defendants conduct business, and a significant part of the acts and conduct complained of herein took place.

45. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Plaintiff

46. Plaintiff purchased CorMedix securities at artificially inflated prices during the Class Period, as set forth in his previously-filed certification (ECF No. 79-1), and was damaged thereby, upon the revelation of the alleged corrective disclosures.

B. Defendants

47. Defendant CorMedix is a biopharmaceutical company that focuses on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases in the U.S. and internationally. The Company is a Delaware corporation with principal executive offices located at 300 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922. The Company has two wholly

owned subsidiaries: CorMedix Europe GmbH (formed in 2013) and CorMedix Spain, S.L.U. (formed in May 2020). The Company's common stock trades in an efficient market on the Nasdaq Stock Market ("NASDAQ") under the ticker symbol "CRMD." Prior to February 2, 2021, the Company's common stock traded on the NYSE American ("NYSE") under the same ticker symbol.

48. Defendant Khoso Baluch ("Baluch") served as CorMedix's Chief Executive Officer ("CEO") and on its Board from October 2016 until he retired, effective October 4, 2021. Prior to joining CorMedix, Baluch served as Senior Vice President ("SVP") and President, Europe, Middle East & Africa, and Chief Marketing Officer of UCB, SA. Baluch also worked for Eli Lilly and Company for 24 years, holding international positions spanning Europe, the Middle East and the U.S. in general management, business development, market access and product leadership.

49. Defendant Robert Cook ("Cook") served as CorMedix's Chief Financial Officer ("CFO") from February 1, 2017, until his employment agreement expired on January 31, 2020. Prior to joining CorMedix, Cook served as CFO of Bioblast Pharma Ltd.; CFO and EVP at Strata Skin Sciences, Inc.; SVP and CFO at Immune Pharmaceuticals, Inc.

50. Defendant Matthew David ("David") has served as CorMedix's CFO and EVP since May 2020. David joined CorMedix after serving as Head of Strategy at Ovid Therapeutics Inc, a late-stage clinical biopharmaceutical company, where he was

responsible for financing strategy and investor relations.

51. Defendant Phoebe Mounts ("Mounts") was, at all relevant times, serving as EVP, General Counsel, and Secretary of CorMedix as well as its Head of Regulatory, Compliance & Legal. Prior to CorMedix, Mounts was a partner at Morgan, Lewis & Bockius LLP, where she had been providing legal services to the Company as outside counsel since 2013, with responsibility for developing its FDA regulatory strategies for Neutrolin.

52. Defendant John L. Armstrong (also referred to as "Jack") ("Armstrong") served as EVP for Technical Operations of CorMedix from March 2017 until his premature retirement, effective October 4, 2021. Prior to that, he was employed by the Company as a consultant beginning in November 2014, performing the same services that he performed as CorMedix's EVP for Technical Operations. The Company touted Armstrong's more than 45 years of experience in the pharmaceutical industry with broad senior level cross functional experience, as well as his having held a number of general management positions. Prior to joining the Company, he was President of Correvio, a private pharmaceutical company supplying product to over 50 countries; President/CEO of Genaera Corporation; SVP of Urocor Corporation; CEO of Mills Biopharma; President of Oread CMO; President of Endo Laboratories (subsidiary of DuPont Merck); President of World-wide Manufacturing for DuPont Merck Pharmaceuticals; and Vice President Operations for Marion/Marion Merrill Dow.

Armstrong also held various roles in manufacturing, quality assurance, led integrated business systems development for three companies as well as having expertise in business development. He is also a CPIM (Certified in Production and Inventory Management).

53. Pursuant to his Employment Agreement with the Company, executed on April 23, 2020, Armstrong was to serve as its EVP for 3 years, until April 2023. In announcing the agreement, CorMedix stated, in relevant part, that his "experience will be critical as we continue our preparations to commercialize Neutrolin, whether on our own or with a strategic or commercial partner."[7]

54. Defendant Joseph Todisco ("Todisco") has served as CorMedix's Chief Executive Officer ("CEO") and on its Board since May 10, 2022. Prior to joining CorMedix, Todisco served as a senior executive at Amneal Pharmaceuticals, where for the past 11 years he held various roles, most recently EVP, Chief Commercial Officer. Prior to that, Todisco was VP, Business Development and Licensing at Ranbaxy, Inc. Todisco was also previously co-founder and managing executive of Gemini Laboratories.

[7] *CorMedix Inc. Announces Contract Extension of Jack Armstrong as Executive Vice President and Head of Technical Operations*, GLOBENEWSWIRE (Apr. 23, 2020, 08:15 ET), https://www.globenewswire.com/news-release/2020/04/23/2020918/0/en/CorMedix-Inc-Announces-Contract-Extension-of-Jack-Armstrong-as-Executive-Vice-President-and-Head-of-Technical-Operations.html.

55. Defendants Baluch, Cook, David, Mounts, Armstrong, and Todisco are referred to herein as the "Individual Defendants", and collectively with CorMedix, are referred to herein as the "Defendants."

IV. FACTUAL BACKGROUND

A. The FDA Approval Process

56. For decades, regulation and control of new drugs seeking to enter the U.S. market has been based on the FDA's approval of the NDA. The FD&C Act prohibits any person from introducing or delivering for introduction an adulterated—*i.e.*, drugs not manufactured in compliance with cGMP—or misbranded drug into interstate commerce.[8] As such, an NDA is required to provide sufficient evidence for the FDA to assess:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- ***Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.***

57. Each NDA must provide certain information relating to the applicant's CMC, including but not limited to, the name and address of each manufacturer of the drug product and drug substance; a description of the manufacturing and packaging procedures and in-process controls for the drug product and drug substance; and the

[8] Section 301(a) of the FD&C Act.

specifications necessary to ensure the identity, strength, quality, purity, and potency of the drug substance and drug product.[9] Data must be available to establish that the analytical procedures used in testing the drug product meet proper standards of accuracy, sensitivity, specificity, and reproducibility and are suitable for their intended purpose.[10]

58. Any party engaged in the manufacture of a drug is responsible for ensuring compliance with cGMP regulations for the manufacturing activities it performs.[11] The FDA's regulations recognize that drug sponsors commonly use contract facilities to perform some drug manufacturing activities.[12] Regardless, if a drug sponsor chooses to use a contract facility, the *drug sponsor* remains legally responsible for assessing the quality of drug products manufactured by the contract facility, including for final release.[13] FDA regulations require that the responsibilities and procedures of the drug sponsor's quality unit be in writing and that they be strictly followed.[14]

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[9] 21 CFR 314.50(d)(1) and 314.94(a)(9)(i).

[10] *See* 21 CFR 211.165(e) and 211.194(a)(2).

[11] *See* Section 501(a)(2)(B) of the FD&C Act; 21 CFR parts 210-211; 600.

[12] 21 CFR 200.10(b) and 211.22(a).

[13] *See* U.S. Food & Drug Admin., *Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry* (Nov. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract-manufacturing-arrangements-drugs-quality-agreements-guidance-industry.

[14] 21 CFR 211.22(d).

59. Therefore, for *both* the drug sponsor and any contract facilities that conduct manufacturing operations, cGMP "includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products."[15] To support proper oversight of manufacturing, quality control labs, quality assurance, regulatory affairs, and project management the drug sponsor's organization should be structured such that:

- Personnel involved in these key areas have relevant knowledge and experience, including technical expertise and authoring capabilities;
- Key oversight roles, including specific sponsor-CMO responsibilities, are well defined in the quality agreement; and
- Appropriate oversight details are documented through Standard Operating Procedures ("SOPs").[16]

60. The FDA encourages drug sponsors and contract facilities to review FDA guidance documents for recommendations on achieving compliance with cGMP.[17] Various FDA guidance documents describe how quality management principles relate

[15] Section 501 of the FD&C Act as amended by the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, Title VII, section 711).

[16] *5 Steps to Quality Oversight of Pharmaceutical Contract Manufacturing Organizations (CMOs)*, COMPLIANCEONLINE https://www.complianceonline.com/resources/quality-oversight-of-pharmaceutical-contract-manufacturing-organizations.html.

[17] *See* U.S. FOOD & DRUG ADMIN., *Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry* (Nov. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract-manufacturing-arrangements-drugs-quality-agreements-guidance-industry.

to contract manufacturing operations, including some of the roles and manufacturing activities of contract manufacturing parties.[18]

61. Likewise, guidances for industry developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH"), and adopted by the FDA, provide specific cGMP guidance with respect to contract manufacturing arrangements.

62. First, ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* states that drug sponsors should evaluate contract facilities to ensure that the sites comply with cGMP for specific operations.[19] In that evaluation, a drug sponsor should learn general prerequisites about a contractor's experience and capabilities, including but not limited to, its:

- understanding of the regulatory environment in which a product will be evaluated;
- proper production environment to meet the product's specific requirements;
- process for authoring and/or transferring documents and/or batch records;
- practical experience relating to product specific analytical methods and validation;
- availability and staffing to formulate and fill when needed;

[18] *See, e.g.,* guidance for industry *Cooperative Manufacturing Arrangements for Licensed Biologics*.

[19] U.S. FOOD & DRUG ADMIN., *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (Sept. 2016), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q7-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients-guidance-industry.

- ability to effectively address and correct manufacturing and/or laboratory issues; and
- system, process and/or procedures for maintaining privacy and confidentiality.[20]

63. ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* also recommends that drug sponsors have approved written agreements with contractors that define the manufacturing responsibilities in detail, including the quality measures, of each party. The written agreements should also describe how changes to processes, equipment, methods, and specifications will be managed and permit the drug sponsor to audit its contractor's facilities for compliance with cGMP. In preparing the written agreements, the drug sponsor should learn about the contractors' prior experience with quality assurance; processes for addressing quality issues; and their ability to author deviations, corrective and preventative actions ("CAPAs"), out-of-specification test results, and/or change controls.

64. Second, ICH guidance for industry *Q9 Quality Risk Management* offers a systematic approach to quality risk management as part of an effective quality

[20] *5 Steps to Quality Oversight of Pharmaceutical Contract Manufacturing Organizations (CMOs)*, COMPLIANCEONLINE https://www.complianceonline.com/resources/quality-oversight-of-pharmaceutical-contract-manufacturing-organizations.html.

system.[21] It discusses quality risk management principles such as risk assessment, risk communication, and risk review and provides examples of tools that can be used to make effective and efficient risk-based decisions in, for example, auditing and arranging quality agreements with contract manufacturers.

65. Third, ICH industry guidance *Q10 Pharmaceutical Quality System* states that, as part of a pharmaceutical quality system, the *drug sponsor* is ultimately responsible for ensuring "processes are in place to assure the control of outsourced activities and quality of purchased materials."[22] Moreover, these processes should incorporate quality risk management and include the following critical activities:

- Assessing the suitability and competence of potential contractors before outsourcing operations or selecting material suppliers. This can be accomplished through audits, material evaluations, or other qualification criteria.
- Defining the manufacturing responsibilities and communication processes for quality-related activities of the involved parties. For outsourced activities, these should be in a written agreement.
- Monitoring and reviewing the performance of the contract facility and identifying and implementing any needed improvements.
- Monitoring incoming ingredients and materials to ensure they are from approved sources using the agreed-upon supply chain.

66. A drug sponsor's "*[s]enior management* has the ultimate responsibility

[21] U.S. FOOD & DRUG ADMIN., *Q9 Quality Risk Management* (June 2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q9-quality-risk-management.

[22] U.S. FOOD & DRUG ADMIN., *Q10 Pharmaceutical Quality System* (Apr. 2009), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q10-pharmaceutical-quality-system.

to ensure an effective pharmaceutical quality system is in place to achieve the *quality objectives*, and that roles, responsibilities, and authorities are defined, communicated, and implemented throughout the company." *Id*. (emphasis in original). As such, senior management should:

- Participate in the design, implementation, *monitoring, and maintenance* of an effective pharmaceutical quality system;
- Demonstrate strong and visible support for the pharmaceutical quality system and ensure its implementation throughout their organization;
- Ensure a *timely and effective communication and escalation process* exists to raise quality issues to the appropriate levels of management;
- Define individual and collective roles, responsibilities, authorities, and inter-relationships of all organizational units related to the pharmaceutical quality system and ensure these interactions are communicated and understood at all levels of the organization;
- Conduct management reviews of process performance and product quality and of the pharmaceutical quality system;
- Advocate for continual improvement; and
- Commit appropriate resources.

67. Senior management is also responsible for establishing a quality policy that describes the overall intentions and direction of the company related to quality. Specifically, the quality policy should include an expectation to comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system. Included in this responsibility, the drug sponsor's senior management must ensure that the quality policy has been communicated to and understood by personnel at all levels in the company and should review the policy periodically for continuing effectiveness and suitability.

68. Likewise, senior management should ensure the quality objectives to implement the quality policy are well defined and communicated; are supported by all relevant levels of the company; align with the company's strategies; and are consistent with the quality policy. Senior management is responsible for providing appropriate resources and training to achieve the quality objectives; and for establishing performance indicators that measure the progress against quality objectives. Performance indicators should be actively monitored and assessed by senior management, regularly communicated, and acted upon as appropriate.

69. A drug sponsor or contract facility may make changes to a drug's manufacturing during the drug development process, such as a new manufacturing site, formulation, purification column, equipment, or components. However, when changes are made, the sponsor and/or contractor must demonstrate that the changes will not have an adverse impact on the drug's quality, safety, and efficacy.

70. Once the NDA has been submitted for review, the FDA may choose to perform a pre-approval inspection ("PAI") to assist in its determination of proper compliance with cGMP regulations.[23] The FDA conducts domestic and international PAIs, and may inspect all facilities associated with an NDA, including drug component manufacturing (such as APIs, also known as, drug substances) and finished drug

[23] Denise DiGiulio, *What to Expect When Being Inspected*, U.S. FOOD & DRUG ADMIN., (July 15-16, 2015), https://www.fda.gov/media/92857/download.

product manufacturing.[24]

71. The PAI process begins with the manufacturing facility obtaining approval of its written procedures related to production, quality control, and quality assurance, and any formulated supporting documentation therefrom.[25] Such written and approved procedures, and data therefrom, are necessary to identify potential quality problems which may link to other major systems for inspectional coverage. When possible, the FDA prefers to verify the manufacturers' adherence to written procedures through an on-site inspection. In advance of a site inspection, the FDA may request and inspect additional records or information within a reasonable timeframe, within reasonable limits, and in a reasonable manner under §704(a)(4) of the FD&C Act.[26]

72. Based on the totality of the information available, including the CMC information provided in the NDA and any additional information about the facility or site, the FDA will take one of the following actions:

[24] U.S. FOOD & DRUG ADMIN., *Compliance Program Guidance Manual – Chapter 46-New Drug Evaluation* (Apr. 12, 2010), https://www.fda.gov/media/71498/download.

[25] U.S. FOOD & DRUG ADMIN., *Compliance Program – Chapter 56 – Drug Quality Assurance, Drug Manufacturing Inspections* (Oct. 31, 2017), https://www.fda.gov/media/75167/download

[26] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Guidance for Industry – Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* (Oct. 2014) https://www.fda.gov/media/86328/download.

Planned Action	Facilities and Sites	Other FDA Drug Assessment Deficiencies
Approve the NDA	Available information supports the adequacy of the facilities and sites named in a pending application.	No deficiencies have been identified and the NDA otherwise satisfies the requirements for approval.
Issue a CRL with facility or site deficiencies	Available information from a prior inspection or other source identifies deficiencies about the facility or site, but the required inspection cannot be completed due to factors including travel restrictions.	If any other deficiencies, are identified by the assessment team, the CRL will include those deficiencies.
Issue a CRL without facility or site deficiencies	An inspection is necessary because there is a lack of information about the facility or site but cannot be completed due to factors including travel restrictions (a facility or site deficiency will NOT be issued; the facility or site issue will be a comment in the CRL).	Other deficiencies are identified by the assessment team. The CRL will contain those deficiencies.
Defer action (i.e., miss the PDUFA date)	An inspection is necessary because there is a lack of information about a facility or site and cannot be completed due to factors including travel restrictions (a facility or site deficiency will NOT be issued).	No deficiencies have been identified, and the application otherwise satisfies the requirements for approval.

73. If the FDA sends the sponsor a CRL, the letter will describe all the specific deficiencies that the FDA identified in the NDA and when possible, recommends actions for the sponsor to take to place its NDA in condition for approval.[27] A sponsor may resubmit its NDA, responding to the deficiencies detailed

[27] Applications for FDA Approval to Market a New Drug, Complete Response Letter to Applicant, 21 C.F.R. §314.110 (2020), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.110 .

in the CRL that needed to be addressed prior to the NDA's approval.[28] Upon receipt of a resubmission, the FDA will determine whether the response is a complete response and if it is, the FDA will issue an acknowledgement letter classifying the resubmission as Class 1 or Class 2, and providing the performance goal date.[29]

74. Pursuant to PDUFA, the FDA reviews and acts on a resubmission within six months. Any resubmission starts a new review cycle – two months for a Class 1 and six months for a Class 2 resubmission – which begins when it is submitted to the FDA. This classification is based on the information submitted in response to a CRL. A Class 1 resubmission may relate to a drug's labeling, safety, stability, validation, post-marketing requirements or commitments, and/or final release testing. A Class 2 resubmission includes any item not specified in Class 1, including items warranting presentation to an advisory committee or a re-inspection.

75. As a result of the COVID-19 pandemic, the FDA made changes to the PAI process and issued multiple temporary guidances related to manufacturing, supply chain and drug inspections during the Class Period.[30]

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[28] CENTER FOR DRUG EVALUATION AND RESEARCH, *Manual of Policy and Procedures - Classifying Resubmissions of Original NDAs, BLAs, and Efficacy Supplements in Response to Complete Response Letters* (effective date Feb. 26, 2015), https://www.fda.gov/media/72727/download.

[29] The Class 1 or Class 2 distinction does not pertain to resubmissions of non-efficacy supplements (*i.e.* labeling and manufacturing supplements). *See* n.15.

[30] U.S. FOOD & DRUG ADMIN., *Manufacturing, Supply Chain, and Drug Inspections | COVID-19* (July 14, 2021) https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19.

76. One change was implementing "an interim process to communicate issues identified following a review of records or other information requested" under §704(a)(4) of the FD&C Act. *Id*. As part of that process, the "FDA intend[ed] to communicate issues to facility representatives following the completion of its review of records or other information requested" and "plan[ned] to consider any formal responses regarding these issues, including documentation of corrective action, prior to taking an action on a pending application impacted by these issues, as feasible given user fee agreement and internal review program milestones." *Id*.

77. In September 2020, the FDA issued industry guidance for resuming normal drug and biologics manufacturing during the COVID-19 pandemic, recommending that manufacturers identify any deviations from established cGMP activities due to COVID-19 as well as any remediation measures taken, and referred them to the previously issued March 2011 industry guidance *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products*.[31] While the September 2020 guidance gave "examples of delayed, reduced, or otherwise modified CGMP activities[,]" it confirmed that "CGMP requirements remain[ed] in effect during the COVID-19 public health emergency and …[wa]s not intended to describe FDA's enforcement priorities." *Id*.

[31] U.S. FOOD & DRUG ADMIN., *Guidance for Industry - Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency* (September 2020) https://www.fda.gov/media/142051/download.

B. Defendants' Fraudulent Scheme to Hide Manufacturing Deficiencies

1. Defendants misled investors about the adequacy of the CMC information the Company provided to the FDA and the commercial readiness of its CMO for the U.S. market, touting its success in other markets and the strength of its team while downplaying early concerns raised by the FDA.

78. Leading up to the Class Period, CorMedix's claimed that its primary focus was on ensuring its manufacturing processes and facilities met FDA standards for U.S. commercialization.

79. At all relevant times, CorMedix's manufacturing processes were outsourced to contract facilities.[32] To select the CMO for its anticipated U.S. commercialization of DefenCath, CorMedix began the evaluation and selection process in late 2016.[33] After contacting and having initial discussions with 13 potential CMOs in the U.S. and internationally, and then conducting site visits, doing initial quality system reviews and reviewing proposals from several of those 13, the Company ultimately selected its CMO, ROVI, in 2017. *Id*.

80. Former Employee ("FE") 1 was a consultant hired by CorMedix to audit their CMO (ROVI) in Spain. From 1988 until 1995, FE1 was a Compliance Investigator with the FDA in New Jersey. FE1 has also worked at Schering Plough as a Good Manufacturing Practices auditor, and at Janssen Pharmaceuticals as a Quality

[32] CorMedix, Inc., Quarterly Report (Form 10-Q) (Nov. 9, 2021).

[33] *See Cormedix, Inc. – Special Call*, REFINITIV STREETEVENTS (Mar. 9, 2021, 01:30PM) ("3/9/21 Call").

and Regulatory Compliance Administrator. FE1 currently owns a company that provides pharmaceutical consultancy services.

81. In 2018, FE1 was hired by CorMedix to do an assessment on ROVI. FE1 was the principal consultant on this audit, which was personally conducted by FE1 and a support team. The audit took a couple of weeks and included an on-site visit to ROVI's facilities in Spain. FE1 indicated that CorMedix had already been using ROVI at the time of the audit.

82. FE2 was the Senior Director of Quality Assurance at CorMedix from February 2020 until they resigned in May 2023. FE2 reported to the Director of Quality, John Ortiz ("Ortiz"), who in turn reported to Defendant Mounts.

83. Prior to the start of FE2's tenure with the Company, in 2018, CorMedix hired FE1 (*see supra* ¶¶80-81) to audit ROVI. FE1 prepared a formal audit report by 2019, wherein he recommended that ROVI not be used, and directly stated that ROVI would never be able to pass an FDA inspection.

84. FE2 explained that despite this finding, ROVI was chosen anyway based on the close personal friendship between ROVI's head and Defendant Baluch.

85. FE2 relayed that FE1's report was placed on an internal Company shared drive, where FE2 was able to access it.

86. FE2 stated Defendant Baluch was closely involved in the production and distribution of FE1's report, and believes that Defendant Mounts received a copy of it.

87. Predictably, said FE2, there were problems with ROVI which began as soon as CorMedix engaged it as CMO. Specifically, the problems were with manufacturing, validation, test methods, and, critically the ROVI facility itself: ROVI had not maintained a sterile manufacturing facility, and its plant was not compliant with International Sterilization Organization standards.

88. Nevertheless, Defendants reiterated time and time again to investors that the Company and its team had the requisite knowledge and experience to oversee and manage the manufacture of Neutrolin (DefenCath). In August 2019, Defendant Armstrong specifically assured investors that:

> **CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites.** This should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it. … And importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved.
>
> … Many companies, particularly small, inexperienced companies, overlook the importance of the CMC section that is required for the NDA. At CorMedix, we have not done that. **We have been diligently working and interacting with the FDA on this topic continually during the product development in the U.S.**
>
> Our press release of July 9 was an update on our ongoing discussions with FDA to ensure that all the CMC information required for the NDA will be in place. It was intended to be **a clear signal from CorMedix to life science investors that we understand the importance of manufacturing data and that we are on top of it.**
>
> In addition, we are now in the process of finalizing the supply chain and

> distribution network for the initial product that will be used for launch in the U.S. The initial finished product will be manufactured in Europe.[34]

89. Then, the Class Period begins on October 16, 2019 with Defendants providing investors with the misleading impression that the FDA was fully on-board with CorMedix's proposed manufacturing program for DefenCath, and NDA approval would come no later than the second half of 2020.

90. Specifically, on that day, the Company declared that "[t]he FDA was supportive of Neutrolin's proposed manufacturing program…. No further CMC meetings with FDA are planned prior to NDA submission."[35] Defendant Baluch added that "Neutrolin can be approved in the second half of 2020[.]" *Id*.

91. In correspondence dated November 7, 2019, the FDA instructed CorMedix to identify all manufacturing facilities associated with the DefenCath NDA and to ensure those facilities be ready for inspection no later than when the Company submitted the DefenCath NDA:

> ***To facilitate our inspectional process, we request that you clearly identify in a single location, either on the Form FDA 356h, or an attachment to the form, all manufacturing facilities associated with your application***. Include the full corporate name of the facility and address where the manufacturing function is performed, with the FEI number, and specific manufacturing responsibilities for each facility. [Exhibit 1 hereto]

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[34] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q2 2019 Results – Earnings Call Transcript*, SEEKING ALPHA (Aug. 13, 2019, 04:30 PM ET), https://seekingalpha.com/article/4285328-cormedix-inc-crmd-ceo-khoso-baluch-on-q2-2019-results-earnings-call-transcript.

[35] 10/16/19 Press Release.

92. While maintaining the false narrative of overwhelming support by the FDA, on November 14, 2019, Defendants informed investors that the agency had asked for additional information.[36] During CorMedix's 3Q19 Call, held on November 14, 2019, Defendant Mounts explained:

> The manufacturing information is closely scrutinized by FDA prior to drug approval to ensure that there are no safety or efficacy [] concern[s]…Just as we have been engaged with FDA on clinical data to support safety and effectiveness of Neutrolin, we have been engaged with the [FDA] and [had] discussions on CMC information.
>
> Manufacturing of the drug product must be shown to be reproducible and reliable through validation study. Stability [a]s a product needs to be demonstrated with extensive data and subject[ed] to conditions likely to be encountered in commercial distribution to ensure the quality as a product. As manufacturing experience expand[s], data on drug substance and drug product are generated and we s[ought] feedback from the FDA in quarter four to discuss the data that have been developed to support the NDA. We believe that **it is important to obtain guidance from FDA to ensure that we have all of the CMC information that the agency is expecting and can proactively address any question FDA may have.**
>
> As we announced the press release on October 16, **FDA provided guidance on the CorMedix CMC program and indicated data that will need to be available in the NDA for [its review]**.[37]

93. Defendant Armstrong also stated during the 3Q19 Call:

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[36] *CorMedix Inc. Reports Third Quarter 2019 Financial Results and Provides Business Update*, GLOBENEWSWIRE (Nov. 14, 2019, 16:05 ET), https://www.globenewswire.com/en/news-release/2019/11/14/1947574/0/en/CorMedix-Inc-Reports-Third-Quarter-2019-Financial-Results-and-Provides-Business-Update.html.

[37] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q3 2019 Results - Earnings Call Transcript*, SEEKING ALPHA (Nov. 14, 2019, 08:45 PM ET) ("3Q19 Call"), https://seekingalpha.com/article/4306874-cormedix-inc-crmd-ceo-khoso-baluch-on-q3-2019-results-earnings-call-transcript.

> The interaction with the FDA [was] on the CMC known as the chemistry manufacturing controls. As [Defendant Mounts] has indicated, is important and critical for the NDA and depending on what is requested [CorMedix] needs to assure [it] completes the work in time to not [delay] the NDA filing. As our press release of 16 October indicated the outcome of our [inter]action with the FDA was very positive. **FDA was supportive of the core manufacturing processes for the drug product and the active pharmaceutical ingredients for the inclusion as part of the NDA submission**.
>
> **FDA did request some additional data** which we are working to complete, so we're optimistic that the CMC module we completed a[s] plan[ned] for filing with the FDA. **FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review.** No further CMC meetings with FD[A] are planned prior to the NDA submission.

94. Defendants' statements led investors to believe that the Company has conducted proper due diligence and quality control of the manufacturing processes and facilities utilized by its CMO contracted for commercial manufacturing in the U.S., ensuring that the CMO's facilities were cGMP-compliant and it was prepared for any type of inspection by the FDA. Further, the Company confirmed that it was "on schedule" for FDA approval in the second half of 2020, in February 2020,[38] and "maintain[ed]" this schedule, in May 2020.[39]

95. Moreover, because Defendants continued to tout the Company's five-year track record of successfully manufacturing and selling Neutrolin in other markets, as well as its top-notch personnel, investors believed CorMedix was well equipped and

[38] 2/3/20 Press Release.

[39] 5/11/20 Press Release.

capable of satisfying regulatory standards and would have no problem providing all necessary CMC information in the DefenCath NDA. Indeed, Defendant Baluch boasted about:

> The significant experience Phoebe [Mounts] brings in regulatory, Jack [Armstrong] in manufacturing and supply chain, Paul in medical affairs and Liz in clinical operation, coupled with my Cialis and Byetta launch experience in the US just to name a few recent launches makes for a winning team. Together, we have a combined experience of over 170 years in the pharmaceutical business.

96. As the COVID-19 pandemic swept through the world in the spring of 2020, Defendants warned of possible delays on the side of the FDA relating to in-person inspections of foreign manufacturing facilities potentially being postponed, but declared that CorMedix and its CMO were "on track" with ensuring the FDA had what it needed to approve the DefenCath NDA by the end of 2020:

- Baluch: "We plan to continue our filing schedule and to be on track for a decision in the second half of 2020, although we cannot at this time anticipate the impact on our timetable of the FDA's postponement of most foreign inspections." (3/16/20 Press Release)
- Mounts: "We cannot predict if this will delay approval of the NDA because pre-approval inspections of the manufacturing facilities relied upon for manufacturing of Neutrolin are required." (4Q19 Call)[40]
- Baluch: "We have remained on schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic." (4/22/20 Press Release)

[40] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q4 2019 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 16, 2020, 04:30 PM ET) ("4Q19 Call"), https://seekingalpha.com/article/4332346-cormedix-inc-crmd-ceo-khoso-baluch-on-q4-2019-results-earnings-call-transcript.

- Mounts: "[W]e are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020. We are all very cognizant of preparing an NDA that is complete and provides all of the information in the agency's required format to ensure an efficient review. We focused on discussions with FDA in 2019 to make sure that we understood the FDA's expectations to evaluate the manufacturing…" (1Q20 Call)
- Baluch: "[T]he effort to move the regulatory process forward with the FDA is on track. We are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020." (1Q20 Call)

97. ROVI's Madrid facility specializes in aseptic filling small volume parenterals in pre-filled syringes and vials, with an annual capacity of 180 million syringes and 50 million vials.

98. By July 8, 2020, CorMedix had completed its rolling submission for the DefenCath NDA, "despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission."[41] The Company assured investors that it "has not been informed of any delays by the FDA in the review of the NDA"[42] and that in order to complete the NDA, the Company "had to work through the [CMC] information[.]"[43]

99. Regardless, and capitalizing on the Company's positive public image following the completion of its NDA submission, on July 27, 2020, CorMedix

[41] 7/8/20 Press Release.

[42] 2Q20 10-Q.

[43] *CorMedix Transcript CEO Khoso Baluch on Q2 2020 Results – Earnings Call*, (Aug. 20, 2020) ("2Q20 Call"), https://seekingalpha.com/article/4367341-cormedixs-crmd-ceo-khoso-baluch-on-q2-2020-results-earnings-call-transcript.

announced its plans to offer shares of its common stock in a public offering.

100. As the FDA continued its review of the DefenCath NDA, CorMedix further informed investors that it was working closely with the agency and was not being told of any issues related to its submission or the FDA's review. For example, on August 31, 2020, when announcing the FDA's acceptance of the NDA for priority review and setting a February 28, 2021 PDUFA date, CorMedix "noted that [the FDA] … had not identified any potential review issues at this time."[44] The Company maintained the same messaging on November 5, 2020 in reporting its 3Q20 financial results, simply warning that it "has not been informed of any delays by the FDA in the review of the NDA, but … pre-approval inspections are required for manufacturing sites."[45]

101. To investors then, the FDA review of the DefenCath NDA (including the manufacturing information) appeared to be going well. Particularly when, on November 18, 2020, CorMedix announced it "has been notified that based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle."[46] At the same time, Defendant Baluch assured investors

[44] 8/31/20 Press Release.

[45] CorMedix, Inc., Quarterly Report (Form 10-Q) (Nov. 5, 2020) ("3Q20 10-Q").

[46] *CorMedix Inc. Announces FDA Decision That Advisory Committee Meeting for New Drug Application for Defencath is Not Needed*, GLOBENEWSWIRE (Nov. 18,

of the high "level of engagement between FDA and the CorMedix team during the NDA review process" and Defendant Mounts confirmed the team's "continu[ed] effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously." *Id*. On these statements, CorMedix's share price rose over 11%.

102. Capitalizing on the continued artificial price of its securities, the Company sold 832,676 shares of common stock in an offering at a weighted average price of $8.69 per share, realizing net proceeds of approximately $7.0 million during 2020. During the first six months ended 2021, the Company sold an aggregate of 3,737,862 shares of common stock at an average price of $11.10 per share, realizing net proceeds of approximately $41.5 million.

103. While Defendants mentioned the request of additional information by the FDA during the Company's October 2019 CMC meeting, at no point did they reveal the severity of those concerns. Nor did they inform investors that the request for additional information was based on identified deficiencies in the manufacturing process, in addition, to mounting deficiencies at the CMO's manufacturing facilities. Because Defendants failed to ensure that the Company's CMO was, and remained,

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2020, 08:30 ET), ("11/18/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/11/18/2129199/0/en/CorMedix-Inc-Announces-FDA-Decision-That-Advisory-Committee-Meeting-for-New-Drug-Application-for-Defencath-is-Not-Needed.html.

cGMP-compliant throughout the collection of information for the submission of the DefenCath NDA and the FDA's review process, the agency observed numerous deficiencies relating to the CMO's facilities and the CMC information provided by the Company.

104. Furthermore, FE2 recalled that during 2021, Ortiz and Reyes Berrios ("Berrios"), another CorMedix executive who worked in Quality Assurance, made multiple trips to Spain in attempts to resolve issues at ROVI.

105. In the First CRL, dated February 26, 2021, the FDA informed CorMedix that DefenCath would not be approved based on i) manufacturing issues that were readily apparent from records provided by ROVI, CorMedix's own CMO; and (ii) a lack of demonstrated manufacturing controls:

> • ***During a review of records requested under Federal Food, Drug, and Cosmetic Act section 704(a)(4), provided by Rovi Pharma Industrial Services S.A. (FEI 3016688535) manufacturing facility, the FDA noted objectionable conditions***. These objectionable conditions will be conveyed to the representative of the facility within 10 business days of issuance of this Complete Response letter. ***Satisfactory resolution of these objectionable conditions is required (e.g., preapproval inspection and/or adequate facility responses addressing these conditions) before this application may be approved***.
>
> • ***You have not demonstrated that the currently proposed in-process control for the [redacted] in the drug product manufacturing process is appropriate. As previously communicated to you, conduct and provide results of an extraction study to demonstrate that the labeled volume of the drug product solution (5 mL) can be consistently withdrawn from vials*** …. [*See* Exhibit 2 hereto at 8-9]

106. Investors were therefore shocked when, before markets opened on March

1, 2021, instead of announcing FDA approval, CorMedix disclosed receipt of the FDA's First CRL, declining approval of the NDA in its present form.[47] The Company explained that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility" and "is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials." *Id*. On this news, CorMedix's stock price fell 54.4%, or $8.16, to close at $6.84 on March 3.

2. After the First CRL, Defendants doubled down on their false narrative that the Company was on track to resolve the manufacturing deficiencies identified by the FDA and resubmit the DefenCath NDA in 2021.

107. Unbeknownst to its investors, however, CorMedix had failed to give a complete picture of what was in the First CRL and continued to downplay its level of involvement and responsibility in the manufacturing process of DefenCath. This is a common practice for drug sponsors that receive CRLs. A cross-sectional study published in April 2015 comparing the content of CRLs and the drug sponsor's associated public announcements found that when press releases were issued, they omitted most of the statements in the CRLs.[48] In the press releases analyzed, only 14%

[47] 3/1/21 Press Release.

[48] Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study. *Compare* Asher Mullard, *Sponsors rarely disclose Refuse to File letters, finds study of regulatory transparency gap in* Nature Reviews – Drug Discovery (Vol. 20, Apr.

of the deficiencies cited by the FDA were noted in the announcement. *Id*. The study concluded that "[p]ress releases are incomplete substitutes for the detailed information contained in [CRLs]." *Id*.

108. In addition to limiting the information disclosed in the First CRL, Defendants knew they still had damage control to do. As analyst Joon Lee of *Truist* noted on March 1, 2021, "CRMD disclosed this AM it has received CRL due to third party manufacturing issues without disclosing the nature of the issue. ***This comes as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).[49]

109. Defendants immediately spoke with Mr. Lee, giving him enough assurances to issue another analyst report that day – one that emphasized that "today's 40% selloff appears overdone" ("3/1/21 *Truist* Report").[50] With regard to the "manual extraction study[,]" the report specifically explained that:

> [M]gmnt stated that the vials contain an 'overage' to ensure that labeled volume can be extracted…. It appears to be a routine process and believes a separate study is unlikely to be needed as long as company can convince

2021) and, Peter Lurie, Harinder S. Chahal, Daniel W. Sigelman, Sylvie Stacy, Joshua Sclar, Barbara Ddamulira, *Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study*, BMJ 2015;350:h2758 (Apr. 8, 2015).

[49] Joon Lee, M.D., Ph.D., Les Sulewski, *CRL Due to CMC Issues. No Deficiencies Related to Efficacy or Safety of Defencath*, TRUIST SECURITIES (Mar. 1, 2021).

[50] Joon Lee, M.D., Ph.D., Les Sulewski, *Selloff on CMC Issues Overdone. REIT BUY But PT To $30 (-$5) On Launch Delays*, TRUIST SECURITIES (Mar. 1, 2021).

> that FDA that the 'overage' included is sufficient to enable extracting of labeled volume.

110. At the same time, the 3/1/21 *Truist* Report confirmed that CorMedix's "Mgmnt was aware that the FDA has requested additional information from the EU based third party manufacturer." *Id.* But Defendants had chosen not to provide investors with this material information earlier, keeping investors in the dark about known concerns raised by the FDA.

111. Thus, despite being forced to disclose manufacturing deficiencies as a result of the First CRL, Defendants tried to soften the blow by slowly releasing disappointing information, intermixed with reinforcements of the Company's management and its CMO's ability to achieve commercialization in the U.S. For example, based on his conversation with the Company's management, Mr. Lee issued yet another analyst report on March 2, 2021 titled "Additional Color from Management on Contract Manufacturer in Question[.]"[51] That report provided that CorMedix "management reiterated that the CMO manufactures drugs sold in the U.S.[,] implying some level of FDA inspection in the past that passed FDA's standards" and "alluded that the CMO is experienced in handling drug/device combos similar in scope to Defencath." *Id.*

112. Internally, said FE2, there were near-constant remediation meetings

[51] Joon Lee, M.D., Ph.D., Les Sulewski, *Additional Color from Management on Contract Manufacturer in Question*, TRUIST SECURITIES (Mar. 2, 2021) ("3/2/21 Trist Report").

following the First CRL, convened on an *ad hoc* basis (sometimes up to four meetings per day) whenever an issue arose. Attendees at these meetings were Defendant Mounts, Ortiz, Berrios and sometimes FE1 and Defendant Baluch.

113. On March 9, 2021, during pre-market hours, CorMedix hosted a special conference call to provide additional color on the FDA's review process, the manufacturing deficiencies identified by the FDA, resulting in the First CRL, and the Company's ongoing collaboration with its CMO to try and address these deficiencies (the "CRL Call"). During that call, Defendant Baluch confirmed that:

> [W]e have received the FDA communication regarding our third-party manufacturing facility and we have been in extensive discussions with the CMO, with the goal of better understanding all of the information submitted to the FDA and the deficiencies identified by the FDA.
>
> We've also been jointly working on draft responses and planned activities to resolve each of the items identified.
>
> The timeline we outlined from our March 1, 2021, press release for a planned meeting with the FDA of mid-April is still valid based on our current understanding and the progress that we have made to date.

114. Defendant Mounts also stated during the CRL Call, in relevant part:

> FDA did not approve the new drug application for DEFENCATH and instead issued a complete response letter because it concluded that the manufacturing facility is not ready to support commercial operations for DEFENCATH. This conclusion was based on a review of records requested by FDA from the CMO…. **FDA began requesting documents from the CMO for a records assessment without doing an on-site inspection and followed up with additional requests to the CMO in the subsequent months. We were also responding to FDA with questions from the review of manufacturing records that CorMedix had submitted in the NDA.**

115. In addition, during the CRL Call, Defendant Armstrong stated, in

relevant part, "**Consistent with industry practice, we continued to work closely with the CMO via site visits and regular conference calls to prepare for an FDA inspection after submission of the NDA**."

116. Defendant Armstrong also added, in relevant part:

> [T]he process CorMedix followed in selecting our drug product CMO. We began the evaluation and selection process in late 2016 because of the long lead time. We had several criteria in the selection process: quality system, capacity and cost. We contacted and had initial discussions with 13 potential CMOs in the U.S. and internationally. After the initial assessments, we narrowed the list of several, including U.S. and international sites for more detailed assessment. We then conducted site visits, did an initial quality system review, reviewed proposals and ultimately selected our CMO in 2017. **We followed the industry standard practice of executing a manufacturing agreement, quality agreement and development of a project plan for technical, analytical transfer and validation with the associated documentation**. Thereafter, we proceeded to execute on the project plan, which included an engineering batch and 3 commercial scale drug product validation batches. *Id.*

117. During the Question-and-Answer ("Q&A") Session of the CRL Call, Defendant Mounts stated, in relevant part:

> **I can confirm that the fill lines are solely for DEFENCATH.** So they're not used for any other product manufacture. As you can imagine, a lot of the information involved in filling lines is proprietary to the facility. **And as you will likely expect, there is a confidentiality agreement in place to protect that information. So I cannot disclose any more specific information about the vial filling line.**

118. Defendants knew or should have known about the deficiencies in the process for withdrawing the labeled volume from vials since before the Class Period when the Company was having CMC discussions with the FDA. Defendants knew

about or recklessly ignored the new equipment being installed at the CMO's facility for another drug product since at least July 2020. Since the CMO manufactured multiple different drug products, Defendants also knew or recklessly ignored that they needed to ensure that its protocols relating to changeover of manufacturing lines and visual inspections of drug products met cGMP standards and that deficient protocols relating to changeover of manufacturing lines and visual inspections of drug products could and would cause contaminated vials, which would delay the CMO's ability to obtain the data requested by the FDA relating to the qualification of the filling operation.

119. During the CRL Call, Defendants also made statements downplaying the issues underlying the First CRL and confirming that the Company's personnel had the skills and experience to successfully resolve the issues, including, *inter alia*:

- Mounts: "Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks."
- Mounts: "For example, one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that ***the equipment is unrelated to the manufacturer of DEFENCATH*** because FDA has requested details to assess the impact to production readiness for DEFENCATH."
- Mounts: "***We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks.***"
- Mounts: "Another deficiency identifies concerns an ***airflow visualization study***, and will likely necessitate repeating the study to demonstrate adequate dynamic conditions in the study, which we believe ***can be accomplished in the next several weeks***."

- Baluch: We believe we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA.[52]

120. Based on these and other statements during the CRL Call, industry analysts following CorMedix believed the manufacturing deficiencies underlying the First CRL were manageable and would be resolved within weeks:

- *JMP*: "Based on the details provided on this morning's conference call, we believe the manufacturing issues are straightforward and can be resolved within weeks."[53]
- *Truist*: "Update Suggest Fixes Are Manageable."[54]
- *Wainwright*: "We did not hear anything on yesterday's call that in our view justifies heightened concern… ."[55]

121. The Company maintained the same messaging on March 30, 2021, during its fourth quarter and full year 2020 ("4Q20") earnings conference call with analysts and investors[56]:

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[52] 3/9/21 Call.

[53] Jason N. Butler, PhD, Roy Buchanan, PhD. *Details on Defencath Manufacturing CRL Issues Support Potential for Rapid Resolution*, JMP SECURITIES LLC ("JMP") (Mar. 9, 2021).

[54] Joon Lee, M.D., Ph.D., Les Sulewski, *Update Suggest Fixes Are Manageable. More To Follow*, TRUIST SECURITIES, INC. (Mar. 9, 2021).

[55] Raghuram Selvaraju, Ph.D., *Update Conference Call Clarifies Regulatory Situation; Reiterate Buy*, H.C. WAINWRIGHT & CO, LLC ("Wainwright") (Mar. 10, 2021).

[56] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q4 2020 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 30, 2021, 06:10 PM ET) ("4Q20 Call"), https://seekingalpha.com/article/4416889-cormedix-inc-crmd-ceo-khoso-baluch-on-q4-2020-results-earnings-call-transcript.

- Baluch: "[W]e have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified."
- Mounts: "The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains ***on track*** based on the progress we have made."
- Mounts: "We make sure that we -- where we could, ***we provided information that was responsive*** to the deficiency."
- Mounts: "[T]he issue was planned expansion at the manufacturing facility, which involved installation of new equipment. That is new equipment non-intended for manufacturer of DEFENCATH. So, ***the information that has been used and is in place is the appropriate equipment*** for DEFENCATH manufacture."

122. Based on these and other statements made by the Company on March 30, 2021, industry analysts continued to believe that CorMedix would resolve the manufacturing deficiencies and resubmit its NDA in May 2021:

- "[O]ur enthusiasm for Defencath remains unchanged, especially in light of no issues found with the drug during the FDA review."[57]
- "[B]ased on mgmnt commentaries, our base case is that CMC issues can be resolved expeditiously without the need for an FDA site visit. We look forward to updates from the mid-April FDA meeting."
- "The company remains on track to meet with the FDA regarding the manufacturing CRL for Defencath in mid-April. We remain of the view … that the deficiencies can be quickly resolved, supporting an NDA resubmission in May."[58]
- "Management commented that it did include new information to address FDA's questions in the meeting request package, further

[69] Joon Lee, M.D., Ph.D.Les Sulewski, *Our Enthusiasm for Defencath Remains Unchanged Despite Cash Overhang and Regulatory Uncertainty*, TRUIST SECURITIES, INC. (Mar. 30, 2021)

[58] Jason N. Butler, PhD, Roy Buchanan, PhD, *4Q20: Update: On the Offensive for Defencath in 2021*, JMP SECURITIES LLC (Mar. 31, 2021).

> reinforcing our view that the [First] CRL can be quickly resolved and the NDA submitted in May."

123. On the same call, a *Truist* analyst observed: "[T]he impression is that it was the [CMO's] deficiencies, so what are you -- why do you need to be involved in addressing their issues? What is it that you can contribute to the CMO's deficiencies?"

124. In response, Defendant Mounts advised:

> I think folks don't understand that there's a parallel process here. As you noted, **we have direct control over documentation and information on manufacturing, that's submitted directly to the new drug application.** As part of that process, FDA inspects the manufacturing facility and reviews documentation and the facility for its ability to manufacture that product in a commercial setting.
>
> **So the inspection by FDA**, whether it's by records assessment or an on- site inspection, **involves reviewing manufacturing records for the product in the NDA, but it also goes broader than that. It goes to the actual facility and the equipment to the maintenance and the training and the personnel.**
>
> So, it's a parallel process, but obviously they are intertwined and can't be separated, because **FDA is there to look at the potential for that facility to manufacture the product that's the subject of the NDA.**

125. However, this enthusiasm was short-lived, when on April 14, 2021, CorMedix announced, representatives from both the Company and its CMO had met with FDA to discuss proposed resolutions for the deficiencies identified in the First CRL and the corresponding Post-Application Action Letter ("PAAL") received by the CMO.[59] That day, the Company was forced to disclose that to meet the FDA's

[59] *CorMedix Has Meeting With FDA on DefenCath Catheter Lock Solution NDA*, GLOBENEWSWIRE (Apr. 14, 2021, 09:00 ET) ("4/14/21 Press Release"),

requirements for the manufacturing process of DefenCath, it would have to take more remedial steps than previously identified. As a result, the Company's NDA resubmission would not occur in May 2021.

126. On this news, the Company's stock price fell over 18%. As analysts following CorMedix noted, "[i]nvestors appear to be responding negatively to the [C]ompany announcing today that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [First CRL] to CorMedix and the Post-Application Action Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath[.]"[60]

127. The 4/14/21 Press Release did, however, provide some assurances regarding the Company's path forward to resubmission. Specifically, Defendants assured investors "[t]here [wa]s now an agreed upon protocol for the manual extraction study identified in the [First] CRL", which CorMedix expected to complete "in the next several weeks." In addition, Defendants stressed that "CorMedix and the CMO continue to work closely to ensure that the identified deficiencies are resolved prior to resubmission of the DefenCath NDA." Industry analysts were thus calmed by the promise of approval before the end of 2021:

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https://www.globenewswire.com/news-release/2021/04/14/2210054/0/en/CorMedix-Has-Meeting-With-FDA-on-DefenCath-Catheter-Lock-Solution-NDA.html.

[60] Amit Chowdhry, *CRMD Stock: Over 10% Decrease Intraday Explanation*, PULSE 2.0 (Apr. 14, 2021) https://pulse2.com/crmd-stock-nasdaq-cormedix-over-10-decrease-intraday-explanation/.

- "We are confident that there is a clear resolution plan agreed upon with the FDA to address the manufacturing CRL… The company and its CMO will complete all of the necessary items to resolve the [First] CRL prior to the resubmission… We are maintaining our base-case view for the launch of Defencath in 4Q21."[61]
- "Based on today's update we anticipate NDA resubmission in the next few months by around 3Q21 followed by FDA decision on the need for a site visit sometime in late 3Q21 or 4Q21[.]"[62]

128. Also on April 14, 2021, the FDA provided new guidance for remote evaluations of drug manufacturing site evaluations to accommodate the challenges of physical site visits during the ongoing pandemic.[63] After speaking to Defendants about this new guidance, *Truist* analyst Lee noted that "[w]e spoke to management this morning on this document. Management believes it certainly opens the door for a virtual visit as opposed to a physical on-site visit…We still believe resubmission is likely in 3Q21 with FDA update in 4Q21."[64]

129. Yet after markets closed on May 13, 2021, investors were surprised to learn that "additional process qualification will be needed with subsequent validation

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[61] Jason N. Butler, PhD, Roy Buchanan, PhD, *Post-FDA-Meeting Update for Defencath*, JMP SECURITIES LLC (Apr. 14, 2021).

[62] Joon Lee, M.D., Ph.D., Les Sulewski, *CRMD Met With The FDA. Need For Site Visit To Be Determined Post NDA Resubmission*, TRUIST SECURITIES, INC. (Apr. 14, 2021).

[63] U.S. FOOD & DRUG ADMIN., *FDA Provides Guidance on Remote Interactive Evaluations for Oversight of Drug Facilities During COVID-19* (Apr. 14, 2021), https://www.fda.gov/news-events/press-announcements/fda-provides-guidance-remote-interactive-evaluations-oversight-drug-facilities-during-covid-19.

[64] Joon Lee, M.D., Ph.D., Les Sulewski, *Path to Remote Virtual Inspection Appears Feasible Based on Recent FDA Guidance*, TRUIST SECURITIES, INC. (Apr. 15, 2021).

to address the deficiencies identified by FDA," preventing CorMedix from being able to resubmit its NDA until 4Q21, eliminating any hopes of approval before the end of 2021.[65] On this news, its stock price fell nearly 20%.

130. Defendants, however, still touted the Company's ability to resolve the manufacturing deficiencies and resubmit its NDA by the end of the year:

- 5/13/21 Press Release: "[W]e have ***the right team*** and resources to accomplish this as we advance DefenCath through the regulatory approval process." (Baluch)
- 1Q21 10-Q: "***The Company and the CMO continue to work closely*** to ensure that the identified deficiencies are resolved prior to resubmission of the DefenCath NDA."
- 1Q21 Call: "[W]e have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiency."
- 8/12/21 Press Release: "CorMedix … remains ***on schedule*** to re-submit the DefenCath™ [NDA] in [4Q21]." (Baluch)[66]
- 2Q21 Call: "[W]e are ***on schedule*** to be able to resubmit the CorMedix NDA in quarter 4, 2021. … We remain confident that we have ***the right team*** and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified[.]" (Baluch)[67]

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[65] *CorMedix Inc. Reports First Quarter 2021 Financial Results and Provides Business Update*, GLOBENEWSWIRE (May 13, 2021 16:01 ET) ("5/13/21 Press Release"), https://www.globenewswire.com/news-release/2021/05/13/2229438/0/en/CorMedix-Inc-Reports-First-Quarter-2021-Financial-Results-and-Provides-Business-Update.html.

[66] *CorMedix Inc. Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update*, GLOBENEWSWIRE (Aug. 12, 2021 16:01 ET) ("8/12/21 Press Release"), https://www.globenewswire.com/news-release/2021/08/12/2280058/0/en/CorMedix-Inc-Reports-Second-Quarter-and-Six-Month-2021-Financial-Results-and-Provides-Business-Update.html.

[67] *CorMedix Inc. (CRMD) CEO Khoso Baluch on Q2 2021 Results – Earnings Call Transcript*, *SEEKING ALPHA* (Aug. 12, 2021) ("2Q21 Call"),

- 2Q21 Call: "[W]e remain ***on schedule*** to resubmit the … NDA in [4Q21]. … [W]e are ***working closely with the[CMO] and CMC consultants engaged by CorMedix*** to ensure that we are addressing FDA concerns appropriately." (Mounts)

131. During the Company's 2Q21 Call, held on August 12, 2021, *Needham* analyst Chad Messer, asked:

> Just wondering about the potential for FDA inspection. I know you guys are hoping -- you don't get one but want to be prepared for one or at least make sure you're -- you do everything you can that your third-party manufacturer is prepared to if you get one. Is it possible for you to give us a little bit of sort of historical perspective on what kind of issues we may or may not have to have to deal with inspection like that?

132. In an effort to qualm any concerns of preparedness or knowledge of what to expect during FDA inspections, Defendant Mounts acknowledged that she had reviewed the FDA database of warning letters from other inspections, and as a result, the areas in which the FDA may have concerns were "obvious" to her:

> There's an abundance of information in FDA database from warning letters, where FDA has gotten and inspected manufacturing facilities. **So it's obvious the kinds of things that the agency looks for when it does an inspection.** So that certainly can provide you with this historical perspective.

133. Thus, industry analysts (and investors) still believed Defendants, particularly because they gave the impression they were intimately involved in resolving the manufacturing deficiencies rather than just leaving it to the CMO:

- "Most importantly, the company is making good progress toward resubmission of the Defencath NDA, including completion of the

https://seekingalpha.com/article/4448910-cormedix-inc-crmd-ceo-khoso-baluch-on-q2-2021-results-earnings-call-transcript.

manual extraction study. The company is advancing process qualification and validation activities, based on which it now expects to resubmit the Defencath NDA in 4Q21. … Additionally, this morning the company appointed a Chief Commercial Officer with deep experience and demonstrated success in the renal disease space."[68]

- "Company remains on track to submit NDA in 4Q21. …[T]he process qualification of vial filling process appears to be in progress by the CMO with inputs from CRMD and outside consultant. The new batches manufactured for these studies will need to undergo new stability tests but mgmnt state that it will not be a rate limiting step to ultimate approvability of DefenCath."[69]
- "The most important update from the quarter was that CorMedix affirmed it remains on track to resubmit in 4Q21 the Defencath NDA for the prevention of catheter-related bloodstream infections."[70]
- "The remaining process qualification and validation work requested by FDA is being completed by the third-party facility, in close collaboration with the CMC and regulatory teams of CorMedix and CMC consultants. CorMedix management affirmed that it remains in agreement with the third-party manufacturer on the appropriate steps to resolve the FDA's concerns. CorMedix is also working with the manufacturing facility to prepare for a potential on-site or remote inspection by the FDA." *Id.*

134. Capitalizing on the continued artificial price of its securities, the Company sold an aggregate of 3,020,340 shares in public offerings and realized net proceeds of $11,415,000 during the six months ended June 30, 2022.[71]

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[68] Jason N. Butler, PhD, Roy Buchanan, PhD, *1Q21 Update: Diligently Advancing to the Defencath NDA Re-Submission*, JMP SECURITIES LLC (Apr. 14, 2021).

[69] Joon Lee, M.D., Ph.D., Les Sulewski, *DefenCath Remains on Track for NDA Resubmission 4Q21. Reit BUY*, TRUIST SECURITIES, INC. (Aug. 12, 2021).

[70] Jason N. Butler, PhD, Roy Buchanan, PhD, *2Q21 Update: On Track for Defencath NDA Resubmission in 4Q21*, JMP SECURITIES LLC (Aug. 13, 2021).

[71] 2022.08.12 2Q22 10-Q.

135. Then on September 7, 2021, during pre-market hours, the Company once again shocked investors revealing that it "ha[d] encountered delays at its third-party" manufacturing facility and "the timeline for CorMedix and the CMO to address deficiencies at the facility that are required for resubmission of the DefenCath NDA [wa]s uncertain[.]"[72] In other words, the "CMO delay br[ought] uncertainty to Defencath NDA resubmission timelines[.]"[73] On this news, CorMedix's stock price fell over 27%.

136. Securities analysts recognized that investors had reacted negatively to the continued unresolved manufacturing deficiencies which were delaying the Company's NDA resubmission.

- CorMedix "slumps 20.6% premarket after the company provided an update with respect to its resubmission timeline for the DefenCath [NDA]."[74]
- CorMedix's "stock was getting crushed on Tuesday, with shares down 23.7% as of 11 a.m. EDT … after the company announced that it 'has encountered delays at its third-party contract manufacturer.' These delays will push back CorMedix's refiling for [FDA] approval of its

[72] *CorMedix Inc. Announces Regulatory Update*, GLOBENEWSWIRE (Sept. 7, 2021, 08:30 ET) ("9/7/21 Press Release"), https://www.globenewswire.com/news-release/2021/09/07/2292524/0/en/CorMedix-Inc-Announces-Regulatory-Update.html.

[73] Jason N. Butler, PhD, Roy Buchanan, PhD, *Defencath Announcement Increases Timing Uncertainty, but Fundamental Impact Unlikely*, JMP SECURITIES LLC (Sept. 7, 2021).

[74] Mamta Mayani, *CorMedix plummets 21% after facing delays at contract manufacturer*, SEEKING ALPHA (Sept. 7, 2021, 09:15 AM ET) ("9/7/21 Seeking Alpha"), https://seekingalpha.com/news/3737518-cormedix-plummets-24-after-facing-delays-at-contract-manufacturer.

> DefenCath antibacterial and antifungal catheter lock solution by an undetermined amount of time."[75]

137. Moreover, the continued delays in resolving the manufacturing deficiencies, resulting in the First CRL, and subsequent delayed resubmission of the DefenCath NDA, indicated that the Company did not have the "right team" to achieve commercialization in the U.S., as confirmed on October 4, 2021.[76] That day, CorMedix announced that, effective immediately, Defendant Baluch was retiring from his role as CEO and resigning from the Company's Board (after being "at the helm" for over five years), and Defendant Armstrong was retiring from CorMedix with Defendant Mounts taking over the Company's "technical operations group, including a group of consultants that are working on addressing the situation with the CMO."[77]

138. Then, on November 9, 2021, during the Q&A Session of the 3Q21 Call, in response to a pre-submitted written question, which recalled that "CorMedix referred to specialized consultants in a recent press release[,]" and asked "how they [we]re

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[75] Keith Speights, *Why CorMedix Stock Is Getting Crushed Today*, THE MOTLEY FOOL (Sept. 7, 2021, 11:20 AM) ("9/7/21 Motley Fool"), https://www.fool.com/investing/2021/09/07/why-cormedix-stock-is-getting-crushed-today/.

[76] *CorMedix Inc. Announces Executive Leadership Changes*, CORMEDIX, INC. (Oct. 4, 2021), https://www.cormedix.com/cormedix-inc-announces-executive-leadership-changes/.

[77] Joseph Sullivan, *A month after a manufacturing hiccup led to a CRL, CorMedix CEO will retire*, ENDPOINTS NEWS (Oct. 5, 2021, 07:20 AM EDT) https://endpts.com/a-month-after-a-manufacturing-hiccup-led-to-a-crl-cormedix-ceo-will-retire/.

assisting the company with the resubmission process[,]" Defendant Mounts confirmed that CorMedix did not have the "right team" stating, in relevant part:

> ***Obviously, we have CorMedix specialists, but because of the importance of these activities*** and the need to have everything done as quickly as possible, ***we have engaged the team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection***.
>
> So, ***we wanted to make sure that we had adequate resources and sufficient knowledge of what FDA will be looking for*** to make sure that we were being comprehensive and complete in all of our activities.

3. Despite reassurances that all manufacturing deficiencies had been resolved, CorMedix received a Second CRL for the same non-compliant CMO – and for a non-compliant API manufacturer.

139. Despite the delays and leadership changes, the market remained hopeful of the Company's ability to achieve FDA approval for DefenCath, largely in part because, Defendants' statements for the remainder of the Class Period provided the false impression that they were turning a corner and were making strides in collecting all necessary data and information that the Company *and* its CMO had to provide the FDA to address the identified manufacturing deficiencies. Indeed, investors were misled into believing that Defendants had made necessary improvements to its management and oversight of the Company's manufacturing processes and contracting facilities, and that once all corrective actions were completed and the NDA resubmitted, there was no risk of CorMedix receiving anything other than FDA approval.

140. In reporting its 3Q21 financial results on November 9, 2021, CorMedix

confirmed it was still working on "address[ing] the deficiencies identified at the manufacturing facility."[78] Likewise, during the 3Q21 earnings conference call, Defendant Mounts specifically noted that:

> As noted by Matt [David], and as we disclosed in early September, there was a delay as a result of issues that the CMO that were unrelated to the manufacture of DEFENCATH. We have been able to resume manufacturing activities and are continuing to complete the work that is required to address the deficiencies identified by the FDA.
>
> Specifically, we have discussed previously that FDA had identified deficiencies involving activities associated with the vial filling line for DEFENCATH at the CMO, in particular, to target filling up volumes.
>
> After analyzing available data, parameters of the filling operation were adjusted, and we determined that qualification of the filling operation was required. It will require some time to complete testing and preparation of documentation to resubmit the manufacturing module of the new drug application or NDA for DEFENCATH.
>
> Until we have completed all of the testing, we will not be able to give specific guidance regarding the timing of resubmission.[79]

141. In addition, during the Q&A Session of the 3Q21 Call, Defendant Phoebe explained that:

> The vial filling activities that we're currently undertaking involve manufacturing of DEFENCATH and it's during that process that we are doing the testing that FDA requires to demonstrate that the process is in fact qualified. So, it's a validation process that's ongoing that actually requires the manufacturing activities, which is why when there was a

[78] *Cormedix Inc. Reports Third Quarter 2021 Financial Results And Provides Business Update*, CORMEDIX, INC. (Nov. 9, 2021), https://www.cormedix.com/cormedix-inc-reports-third-quarter-2021-financial-results-and-provides-business-update/.

[79] CorMedix Inc., *CEO Matt David on Q3 2021 Earnings Call Transcript* (Nov. 09, 2021, 07:58 PM ET) ("3Q21 Call"), https://seekingalpha.com/article/4467632-cormedix-inc-crmd-ceo-matt-david-on-q3-2021-earnings-call-transcript.

delay, we had a problem in doing the manufacturing.

> So, now that the manufacturing has resumed, we can continue generating the data and the documentation that we need to submit to FDA. And the new batches are part of that process. So, obviously, we're manufacturing batches as we go and analyzing those batches to collect the data and can generate documentation.

142. One analyst noted that a key takeaway from the 3Q21 Call was the fact that "CorMedix and its CMO ha[d] now resumed manufacturing activities to address the [First] CRL and [we]re advancing towards resubmission of the DefenCath NDA."[80] Further, *JMP* analysts professed that they "again confirmed that there remain[ed] clear alignment between FDA, CorMedix, and its CMO on the strategy and activities needed to address the [First] CRL items, and the companies [we]re working collaboratively to complete this work." *Id*.

143. On January 6, 2022, *Truist* analysts issued some "Quick Thoughts" following a conversation with CorMedix management earlier that day.[81] Specifically, the report highlighted the completion of the manual extraction study and the resolution of the identified deficiencies at the CMO's facilities. Based on that conversation, *Truist* analysts anticipated the DefenCath NDA would be resubmitted in the first half of 2022.

144. Then, on February 28, 2022, CorMedix announced that it had resubmitted the DefenCath NDA to address the manufacturing deficiencies identified

[80] Jason N. Butler, PhD, Roy Buchanan, PhD, *3Q21 Update Manufacturing Activities Restarted for Defencath*, JMP SECURITIES LLC (Nov. 10, 2021).

[81] Joon Lee, M.D., Ph.D., Les Sulewski, *CMC Back on Track and NDA Resubmission Possible 1H22*, TRUIST SECURITIES, INC. (Jan. 6, 2022).

by the FDA a year prior.[82] The 2/28/22 Press Release quoted Defendant Mounts as stating that "[t]he CorMedix team will continue to work collaboratively with FDA and [its] [CMO]" and that "we and the manufacturer have adequately addressed the concerns the [FDA] identified in the [First] CRL."

145. Industry analysts following CorMedix immediately issued glowing reports in response to this false assurance that problems relating to manufacturing were now a thing of the past. For example, *JMP* analysts highlighted that CorMedix "[m]anagement is confident that it and its third-party manufacturer have addressed all of the FDA's concerns" and relayed that CorMedix "indicate[d] that it plans to continue to work collaboratively with the FDA and its contract manufacturer regarding the NDA submission/review and the responses to the PAAL."[83] Because "the [C]ompany and its manufacturing partner gained clear alignment with the FDA on steps needed to address the CRL questions," the *JMP* analysts "remain[ed] confident in a high probability of approval." *Id.*

146. Similarly, *Truist* analysts noted that the day's news was "a huge relief"

[82] *Cormedix Inc. Announces Resubmission of New Drug Application for Defencath*, GLOBENEWSWIRE (Feb. 28, 2022) ("2/28/22 Press Release"), https://www.globenewswire.com/news-release/2022/02/28/2393197/0/en/Cormedix-Inc-Announces-Resubmission-of-New-Drug-Application-for-DefenCath.html.

[83] Jason N. Butler, PhD, Roy Buchanan, PhD, *DefenCath NDA Re-Submission a Positive Start to 2022*, JMP SECURITIES LLC (FEB. 28, 2022).

after "some drama and recent change of leadership."[84] They further noted that "previously, the [CorMedix] mgmnt stated that the NDA can be resubmitted without completion of full stability test," but "then, the Street learned that the FDA requested an 'in-process qualification study' / 'manual extraction study' which necessitated production of new batches and new stability tests." *Id.*

147. Then, on March 28, 2022, CorMedix announced that the DefenCath NDA resubmission had been accepted for filing as a Class 2 response, warranting a 6-month review cycle, including an advisory committee presentation or re-inspection.[85] Defendant Mounts is quoted in the 3/28/22 Press Release as stating "***CorMedix and our [CMO] have adequately addressed the concerns the [FDA] identified during the review of the original NDA and we are committed to working jointly to ensure a successful inspection.***"

148. Likewise, the next day, during the Company's conference call for the fourth quarter of 2021, Defendant Mounts stated that "CorMedix and the [CMO] have adequately addressed the concerns identified by FDA…" and that ***"[w]e are committed to providing updates to investors as appropriate over the coming months during the***

[84] Joon Lee, M.D., Ph.D., Les Sulewski, *DefenCath NDA Resubmitted. Not out of The Woods But Moving in Right Direction*, TRUIST SECURITIES, INC. (Feb. 28, 2022).

[85] *CorMedix Inc. Announces FDA Acceptance of Resubmission of New Drug Application for Defencath*, GLOBENEWSWIRE (Mar. 28, 2022) ("3/28/22 Press Release"), https://www.globenewswire.com/news-release/2022/03/28/2411002/0/en/CorMedix-Inc-Announces-FDA-Acceptance-of-Resubmission-of-New-Drug-Application-for-DefenCath.html.

review process."[86] She also emphasized that "it is important to anticipate ***potential supply chain challenges and ensure multiple sources are in place to provide adequate inventory."*** *Id.*

149. At the time those statements were made, Defendants CorMedix and Mounts knew or recklessly ignored that the Company's CMO was not meeting cGMP standards, and that the FDA had observed manufacturing deficiencies at the third-party facility supplying one of the key active pharmaceutical ingredients (API) of DefenCath, heparin, for the U.S. market. Indeed, unbeknownst to investors, those same deficiencies had resulted in the issuance of a Form 483 by the FDA on February 4, 2022, to the Company's API manufacturer, and warranted requests for corrective actions, yet, Defendants said nothing.

150. As a result of these misleading statements, analysts "remain[ed] confident that there is clear alignment between the FDA, CorMedix, and its [CMO] on the necessary information to address the CRL." Further, since "the FDA has scheduled an onsite inspection of the [CMO]," analysts were "confiden[t] that the manufacturing items in the CRL can be fully addressed ahead of the PDUFA date."[87]

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[86] *CorMedix Inc. (CRMD) CEO Matt David on Q4 2021 Results – Earnings Call Transcript*, SEEKING ALPHA (Mar. 29, 2022) ("4Q21 Call"), https://seekingalpha.com/article/4498557-cormedix-inc-crmd-ceo-matt-david-on-q4-2021-results-earnings-call-transcript.

[87] Jason N. Butler, PhD, Roy Buchanan, PhD, *4Q/FY21: DefenCath NDA Review Underway for Likely Approval This Year*, JMP SECURITIES LLC (MAR. 30, 2022).

151. The charade continued after Defendant Todisco took the helm. Indeed, *Truist* analysts "view[ed] his onboarding as a positive sign for CRMD and DefenCath" because they "expect[e]d Mr. Todisco to have done a fair amount of due diligence before deciding to join CRMD at such a critical juncture."[88]

152. In his first opening remarks as CEO, which was during the Company's conference call for the first quarter of 2022, held on May 12, 2022, Defendant Todisco stated that "any FDA inspection of our CMO will assess the commercial readiness of the facility and manufacturing operations beyond those specific to DefenCath."[89] Defendant Todisco went on to add that "an ongoing work stream to identify U.S.-based CMOs that could be utilized for expanded manufacturing capacity to support commercial launch and for development of a pre-filled syringe format" but omitted that Defendants had no evidence that it had resolved the "objectionable" manufacturing deficiencies the FDA privately told CorMedix had to be fixed before the DefenCath NDA could be approved.

153. In addition, at no time during the 1Q22 Call did Defendant Todisco disclose the already materialized risk of failing to achieve FDA approval as a result of

[88] Joon Lee, M.D., Ph.D., Les Sulewski, *Incoming CEO With Strong Commercial Background Bodes Well For DefenCath*, TRUIST SECURITIES, INC. (Mar. 29, 2022).

[89] *CorMedix Inc. (CRMD) CEO Joe Tosdico on Q1 2022 Results – Earnings Call Transcript*, SEEKING ALPHA (May 12, 2022) ("1Q22 Call"), https://seekingalpha.com/article/4510981-cormedix-inc-crmd-ceo-joe-todisco-on-q1-2022-results-earnings-call-transcript.

the major manufacturing deficiencies identified at the facility manufacturing CorMedix's key API, heparin. Indeed, Defendant Todisco failed to disclose material information when he specifically referenced the "continuing initiatives to dual source key components and active ingredients in order to de-risk … potential governmental regulatory actions at any key supplier" and purported to respond to a specific question about "what kind of preparations [the Company was] making in terms of launch in terms of commercial prep and manufacturing supply ahead of time." Instead of disclosing the high risk to the DefenCath NDA resulting from the known manufacturing deficiencies at the Company's API supplier, Defendant Todisco simply stated that "in terms of activities that we are currently undertaking, we are doing right now all the typical prelaunch planning."

154. Likewise, Defendant Todisco omitted disclosure when he presented at the June 15, 2022 JMP Securities Life Sciences Conference – despite being told that investors "are focused on the manufacturing inspection process" and being specifically asked "[i]s everything there moving forward and still gives you confidence that [FDA inspection] can be completed in time to enable an approval later this quarter?"[90] Although he knew that CorMedix had not obtained the evidence that the manufacturing deficiencies had been resolved, as the FDA privately told Defendants would be

[90] Edited Transcript, CRMD.OQ – CorMedix Inc at JMP Securities Life Sciences Conference REFINITIV STREETEVENTS (Jun. 15, 2022, 02:30PM) ("JMP Transcript").

required before approval, Defendant Todisco double-downed on the Company's CMO and its ability to maintained cGMP standards, stating, "our contract manufacturer is a reputable – highly reputable European manufacturer. I think they're going to take all care to work diligently through any observation and work with the FDA on, if necessary, improving any compliance concerns FDA could raise." And when followed up with the question, "has the company addressed all the questions appropriately?" Defendant Todisco provided a resounding "Yes, yes."

155. Defendants' statements thus conveyed to investors that the Company had closely worked with its third-party manufacturers and suppliers to ensure that it could finally demonstrate that it could manufacture DefenCath for commercial use according to cGMP standards. As *Truist* analysts noted, "[w]ith CMC issues likely in the rear-view, CRMD is making several strategic moves that bolsters our confidence in commercial prospects of DefenCath."[91]

156. As Defendants (but not investors or analysts) knew, however, their CMO still had manufacturing deficiencies, as did CorMedix's heparin producer. As a result, CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved." On August 4, 2022, CorMedix received the Second

[91] Joon Lee, M.D., Ph.D., Les Sulewski, *Strong Mgmnt And SAB Bolsters Commercial Outlook For DefenCath Ahead of Late 3Q22 PDUFA*, TRUIST SECURITIES, INC. (May 12, 2022).

CRL from the FDA, pointing out these deficiencies while further noting the Company's failure to coherently designate its manufacturers in FDA submissions.

> • During a recent inspection of the [heparin facility] and Rovi Pharma Industrial Services S.A (FEI 3016688535) manufacturing facilities for this application, ***our field investigators conveyed deficiencies to the representatives of the facilities. Satisfactory resolution of these deficiencies is required before this application may be approved***.
>
> • ***There are facilities (e.g., release/stability testing sites) included in DMF [or "Drug Master File"] … for HEPARIN SODIUM [redacted] that were not listed in your application*** (i.e., Form FDA 356h and/or in Section 3.2.S.2.1). Please note that the FDA cannot provide to you the status of facilities not listed in your application. Please contact the DMF holder to identify and resolve any discrepancies and clarify which facilities listed in the DMF support your application. We recommend that the DMF related facilities supporting your application be added to your Form FDA 356h and in Section 3.2.S.2.1. If only a subset of the facilities listed in the DMF will be referenced in your application to support commercial manufacturing and/or testing, the letter of authorization (LOA) should specify those facilities. Absent this specificity, the FDA intends to assume that all facilities listed in a referenced DMF support your application. [*See* Ex. 2 at 2, 5]

157. Four days later, on August 8, 2022, CorMedix finally disclosed that its CMO still had manufacturing deficiencies *via* its announcement of a Second CRL "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA."[92]

158. Despite receiving the First CRL as a result of identified deficiencies in the manufacturing of another drug at its contractor's facility, CorMedix failed to sufficiently prepare for "the FDA conduct[ing] a recent inspection unrelated to

[92] 8/8/22 Press Release.

DefenCath at the facility of the company's heparin supplier, which culminated in the API supplier receiving a warning letter as a result of manufacturing deficiencies for a non-heparin API." As a result, "by way of the CRL, the FDA has now informed the company that satisfactory resolution of these deficiencies will be required before the DefenCath NDA may be approved."

159. This news caused CorMedix's stock price to fall over 57%, causing Plaintiff and the putative class to suffer significant losses and damages.

160. If Defendants disagreed with either the First or Second CRL, they were entitled to appeal. "FDA regulations 21 CFR 312.48 and 21 CFR 314.103 address dispute resolution as it relates specifically to … new drug applications (NDA)[.]"[93] That they did not even attempt to do so constitutes an admission that Defendants knew the manufacturing deficiencies flagged by the FDA were material.

4. Since Defendants concealed the identity of the Company's CMO and heparin manufacturer for commercialization in the U.S, throughout the Class Period, investors were in the dark about their lack of experience with FDA inspections and inability to maintain cGMP standards, and ensuing risk to the DefenCath NDA.

161. Throughout the Class Period, Defendants knew, but did not disclose, the identity of CorMedix's CMO and heparin manufacturer, thus leaving investors in the dark about risks related to both manufacturers until they materialized and were

[93] U.S. Food and Drug Administration, CDER Formal Dispute Resolution, https://www.fda.gov/about-fda/cder-contact-information/cder-formal-dispute-resolution

disclosed by Defendants. Nonetheless, Plaintiff's investigation and Defendants' own admissions later uncovered which CMO and heparin manufacturer contracted with CorMedix. ROVI, CorMedix's CMO, had very limited prior experience with FDA inspections and their manufacturing processes and protocols did not comply with certain cGMP standards during the Class Period, as seen in the FDA's on-site inspections.

162. In May 2020, CorMedix formed a wholly-owned subsidiary in Madrid, Spain while the country was beginning to ease its COVID-19 lockdown restrictions. Unbeknownst to investors at the time, CorMedix had done so because ROVI is located there

163. By July 9, 2020, Defendants knew or recklessly ignored that ROVI had agreed to do "large-scale, commercial fill-finish manufacturing of Moderna's" COVID-19 vaccine candidate at ROVI's Madrid facility.[94] As part of the deal, ROVI was to "provide vial filling and packaging capacity by procuring **a new production line and equipment for compounding, filling, automatic visual inspection and labeling** to support production of hundreds of millions of doses of the vaccine candidate … to supply markets outside of the U.S. starting in early 2021." *Id.* Based

[94] ROVI, *Moderna and ROVI Announce Collaboration for Outside the United States Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate* (Jul. 9, 2020), https://roviservices.com/wp-content/uploads/2020/12/ROVI_Press-release_Moderna_1.pdf.

on FDA guidelines and/or communications with the FDA (*see supra* ¶¶56-76), CorMedix knew or should have known that it needed to provide to the FDA, information about any new production line and/or equipment at the facility manufacturing DefenCath – even if it was unrelated to the manufacturing of DefenCath.

164. On March 9, 2021, CorMedix disclosed the "proposed future installation of new equipment" at its CMO's facility as well as "delays" at its CMO relating to "issues … unrelated to DefenCath manufacturing activities" on September 7, 2021. These disclosures corresponded most closely to what was happening at ROVI with regard to its manufacturing for Moderna during that time.

165. By April 29, 2021, Defendants knew or recklessly ignored that ROVI would be investing in new production lines at its Madrid facility "where it bottles, or 'fills and finishes' Moderna vaccines for markets" other than the US in order to "double its capacity to bottle" the vaccine.[95] Again, based on FDA guidelines and/or communications with the FDA (*see supra* ¶¶56-76), CorMedix knew or recklessly ignored that it needed to provide the FDA information about any new production lines at the facility manufacturing DefenCath – even if they were unrelated to the

[95] Reuters, *Spain's Rovi Will Double Its Capacity to Bottle Moderna's COVID-19 Vaccines*, U.S. NEWS (Apr. 29, 2021, 02:52 AM), https://www.usnews.com/news/world/articles/2021-04-29/spains-rovi-will-double-its-capacity-to-bottle-modernas-covid-19-vaccines.

manufacturing of DefenCath.

166. By July 27, 2021, Defendants knew or recklessly ignored contaminants in vials manufactured by ROVI, which required ROVI to conduct testing, as Moderna had publicly warned customers outside the U.S. of temporary delays in its COVID-19 vaccine shipments resulting from a testing operation by overseas manufacturing partners – one of whom was known to be ROVI.[96] Based on FDA guidelines (*see supra* ¶¶56-76) and/or communications with the FDA, CorMedix knew or should have known that it needed to provide the FDA with information about testing being done at the facility manufacturing DefenCath – even if it was unrelated to the manufacturing of DefenCath.

167. By August 26, 2021, Defendants knew or recklessly ignored that Japan had halted the use of over 1.6 million doses of Moderna's COVID-19 vaccine after "[u]nspecified contaminants were discovered in nearly 40 doses of the vaccine at eight locations across Japan, prompting the decision to pull the lot that included them, as well as two other lots produced at the same location[.]"[97] Later that day, ROVI admitted that "the origin of this incident may be in one of its manufacturing lines and it was

[96] *Moderna warns of Covid-19 vaccine delivery delays for customers outside US*, RT.com (Jul. 27, 2021, 18:43), https://www.rt.com/news/530406-moderna-covid-vaccine-delivery-disruption/.

[97] Ben Dooley and Hisako Ueno, *Japan halts 1.6 million doses of the Moderna vaccine over contamination worries*, THE NEW YORK TIMES (Oct. 28, 2021) https://www.nytimes.com/2021/08/26/world/japan-moderna.html.

conducting an investigation following the standard procedure for such cases" as well as putting on hold "two adjacent lots … as a precaution."[98]

168. By September 1, 2021, Defendants knew or recklessly ignored the results of ROVI's investigation as they were made public.[99] ROVI's root cause analysis report identified "the most probable cause of the particulates" as "related to friction between two pieces of metal installed in the stoppering module of the production line due to an incorrect set-up. The two pieces are the star-wheel and the stoppers feeding device piece which feeds stoppers into the star-wheel." ROVI believed "that this condition occurred during the assembling of the line prior to production of [the impacted batch] and was a result of improper alignment during a line changeover before starting this batch." *Id*. Moderna independently analyzed and confirmed that the particulate were grade 316 stainless steel, which was consistent with the root cause investigation. *Id*. ROVI took the following steps to correct and prevent future defects:

- Full inspection of the manufacturing line;
- Improving standard operating procedure for changeover of manufacturing

[98] Clara-Laeila Laudette, *Rovi investigating possible Moderna vaccine contamination, no safety issues so far*, REUTERS (Aug. 26, 2021, 12:27 PM EDT), https://www.reuters.com/world/europe/rovi-investigating-possible-moderna-vaccine-contamination-no-safety-issues-so-2021-08-26/.

[99] *Laboratorios Farmaceuticos Rovi S A : ROVI informs about the joint statement from Moderna and Takeda on the investigation of suspended lots of the vaccine*, MARKETSCREENER (Sept. 1, 2021, 03:52 PM EST), https://www.marketscreener.com/quote/stock/LABORATORIOS-FARMACEUTICO-388853/news/Laboratorios-Farmaceuticos-Rovi-S-A-ROVI-informs-about-the-joint-statement-from-Moderna-and-Takeda-36303039/.

line; and

- Setting alert inspection limits in the automatic visual inspection, as an internal process control. *Id.*

169. By October 1, 2021, Defendants knew or recklessly ignored that ROVI had discovered contaminants in some vials in July 2021, and allowed supplies from that same production to pass inspection and ship to Japan.[100]

170. By October 21, 2021, Defendants knew or recklessly ignored that the FDA had delayed granting marketing authorization for Risperidone ISM, an injectable antipsychotic for the treatment of schizophrenia in the research phase, pending an on-site inspection of ROVI's manufacturing facility in Spain in light of outstanding concerns.[101] Previously on September 24, 2021, ROVI had received a CRL from the FDA citing outstanding questions relating to the documents submitted in support of its marketing authorization application. ROVI admitted to only addressing some, not all, of the FDA's noted concerns.

171. By April 8, 2022, Defendants knew or recklessly ignored that ROVI had announced a recall of a lot of the Moderna COVID-19 vaccine due to a foreign body

[100] Rocky Swift, *Japan's Takeda says 'human error' caused contamination of Moderna vaccines*, REUTERS (Oct. 1, 2021, 01:17 AM EDT), https://www.reuters.com/world/asia-pacific/japans-takeda-says-human-error-caused-contamination-moderna-vaccines-2021-10-01/.

[101] ROVI, *FDA delays its decision on Respiradone ISM®*, ROVI.ES (Oct. 21, 2021, 15:42), https://www.rovi.es/en/content/fda-delays-its-decision-risperidone-ismr.

being found in a vial, manufactured at ROVI's facility in Spain.[102] While no safety concerns had been reported in individuals who received the vaccine from this lot, out of an abundance of caution, the company initiated the recall.

172. By June 27, 2022, Defendants knew or recklessly ignored that the FDA had audited ROVI "and issued inspectional observations (*via* FDA Form 483)."[103] This inspection appears to have been the PAI that Defendants claimed to have prepared for after receiving the First CRL.

173. Because Defendants did not disclose the identity of CorMedix's CMO and/or other material facts about the CMO's lack of experience with FDA inspections and maintaining cGMP standards when adding new production lines and equipment or changing drug products in the manufacturing line, investors had no reason to expect the First CRL, delays in the resubmission due to manufacturing deficiencies related to the CMO's process for manufacturing DefenCath and protocols relating to changeover of manufacturing lines and visual inspections of drug products, nor did they expect receipt of the Second CRL. Defendants compounded investors' confusion by touting the Company's successful interactions with the FDA and manufacturing of DefenCath.

174. According to FE2, CorMedix's heparin suppliers during the Class Period

[102] ROVI, Recall Notification of Lot #0000190A, ROVI.ES (Aug. 4, 2022), https://www.rovi.es/en/content/recall-notification-lot-000190a.

[103] *483 Laboratorios Farmaceuticos Rovi S.A., Jun 2022*, FDAzilla.com, https://fdazilla.com/store/form483/3010705046-20220627.

were Pfizer and Navitas.

175. The NDA had been submitted identifying one API (supplier), but CorMedix then attempted to use two suppliers.

176. Each company manufactured a different vial size. One was 3ml and the other utilized a 5ml vial. The NDA had specified only one supplier and a certain vial size. This is why the FDA required that CorMedix identify a particular heparin supplier and resubmit the NDA. *See* ¶156, above.

177. FE2 related that CorMedix needed a second supplier due to their inability to get the Pfizer heparin into Spain owing to a customs issue involving CorMedix's lack of an export agent. CorMedix then tried to revert to Navitas, as its primary heparin supplier, thus creating additional problems with the FDA.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD[104]

178. The Class Period begins on October 16, 2019, when pre-market, the Company issued a press release entitled "CorMedix Completes Successful CMC Interaction with the FDA." That same day, the Company filed the 10/16/19 Press Release with the SEC as Exhibit 99.1 to the Current Report on Form 8-K, signed by Defendant Cook pursuant to the requirements of the Exchange Act. The 10/16/19 Press Release stated, in relevant part, that:

[104] In this Section, the alleged false and/or misleading portions of the statements are both bolded and italicized.

> ***The FDA was supportive of Neutrolin's proposed manufacturing program***, including the active pharmaceutical ingredients (API), the container closure and testing, and ***indicated that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of NDA filing. No further CMC meetings with FDA are planned prior to NDA submission.***

179. Defendant Baluch was further quoted in the 10/16/19 Press Release as stating that "[w]e anticipate that ***Neutrolin can be approved in the second half of 2020*** and we intend to launch Neutrolin commercially in the US promptly after its approval either by ourselves or with a partner."

180. The statements referenced in ¶¶178-179 were materially false and misleading and/or omitted material facts, including that: (i) the FDA raised concerns regarding the CMC information presented, including but not limited to, quality control data, and requested additional data be submitted with the NDA; (ii) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) Defendants had failed to ensure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

181. On November 14, 2019, the Company issued its 3Q19 Press Release that announced, in relevant part:

> ***The FDA was supportive of Neutrolin's proposed manufacturing program***, including the manufacture of the active pharmaceutical ingredients (APIs), the container closure and testing, and ***indicated that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA filing. No further CMC meetings with the FDA are planned prior to the NDA submission***.

182. The statements referenced in ¶181 were materially false and misleading and/or omitted material facts, including that: (i) Defendants had downplayed the true scope of the FDA's request for more data; (ii) the FDA raised concerns regarding the CMC information presented, including but not limited to quality control data, and requested additional data be submitted with the NDA; (iii) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iv) Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (v) therefore, the additional data CorMedix and it's CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (vi) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

183. Later that day, the Company hosted its 3Q19 Call with investors and

analysts at 4:30 ET to discuss, among other things, its 3Q19 financial results. During the call, Defendant Mounts explained:

> Manufacturing of the drug product must be shown to be reproducible and reliable through validation study. Stability [a]s a product needs to be demonstrated with extensive data and subject[ed] to conditions likely to be encountered in commercial distribution to ensure the quality as a product. ***As manufacturing experience expand[s], data on drug substance and drug product are generated and we s[ought] feedback from the FDA in quarter four to discuss the data that have been developed to support the NDA.*** We believe that it is important to obtain guidance from FDA to ensure that we have all of the CMC information that the agency is expecting and can proactively address any question FDA may have.
>
> As we announced the press release on October 16, ***FDA provided guidance on the CorMedix CMC program and indicated data that will need to be available in the NDA for [its review]***.

184. In addition, during the 3Q19 Call, Defendant Armstrong stated, in relevant part:

> The interaction with the FDA [was] on the CMC known as the chemistry manufacturing controls. As Phoebe as indicated***, is important and critical for the NDA and depending on what is requested [CorMedix] needs to assure [it] completes the work in time to not [delay] the NDA filing.*** As our press release of 16 October indicated the outcome of our [inter]action with the FDA was very positive. FDA was supportive of the core manufacturing processes for the drug product and the active pharmaceutical ingredients for the inclusion as part of the NDA submission.
>
> ***FDA did request some additional data which we are working to complete, so we're optimistic that the CMC module we completed a[s] plan[ned] for filing with the FDA. FDA did indicate that it will conduct a thorough review of all of the CMC information as well as assess the commercial readiness of the various manufacturing facilities at the time of the NDA review. No further CMC meetings with FD[A] are planned prior to the NDA submission.***

185. Defendant Armstrong went on to add, in relevant part, that:

> …As mentioned previously, ***I have working with me a very experienced and competent team, they have the needed breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance that is necessary for both the US and foreign markets.***
>
> * * *
>
> [T]he drug product manufacturer, that's [the vial] is in place and ***processes have been established and appropriate validation testing completed to enable manufacture of launch quantities.***

186. The statements referenced in ¶¶183-185 were materially false and misleading and/or omitted material facts, including that: (i) Defendants had downplayed the true scope of the FDA's request for more data; (ii) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) likewise, the FDA raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iv) CorMedix's "team", including the Individual Defendants, failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (v) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

187. On February 3, 2020, during pre-market hours, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin New Drug Application" ("2/3/20 Press Release"). That press release stated, in relevant part, that "***CorMedix remains on schedule for a potential NDA approval during the second half of 2020***."[105]

188. The statement referenced in ¶187 was materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were

[105] *CorMedix Inc. Announces FDA Grant of Rolling Review of Neutrolin® New Drug Application*, GLOBENEWSWIRE (Feb. 3, 2020, 08:15 ET) ("2/3/20 Press Release"), https://www.globenewswire.com/news-release/2020/02/03/1978704/0/en/CorMedix-Inc-Announces-FDA-Grant-of-Rolling-Review-of-Neutrolin-New-Drug-Application.html.

adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

189. On March 16, 2020, CorMedix filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2019,[106] filed with the SEC on March 16, 2020, signed by Defendants Baluch, Kaplan, Dillione, Dunton, Khan, and Lekfowitz. The 2019 10-K included certain "Risks Related to Dependence on Third Parties" which unbeknownst to investors, had already materialized.

190. First, the 2019 10-K warned that "***[d]ata provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete***." Specifically, it stated that "[w]e rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. ***If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.***"

191. Second, the 2019 10-K warned that:

> Our contract manufacturers ***may not be able to comply with the applicable FDA regulatory requirements***, ***which could result in delays to our***

[106] CorMedix, Inc., Annual Report (Form 10-K) (Mar. 16, 2020) ("2019 10-K").

> ***product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval.*** They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our product candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. ***If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP***, ***we may experience manufacturing errors resulting in*** defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, ***delay or prevention of filing or approval of marketing applications for our products,*** cost overruns or other problems that could seriously harm our business. ***Not complying with FDA requirements could*** result in a product recall or ***prevent commercialization of our product candidates and delay our business development activities.*** In addition, ***such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including*** recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, ***refusal to approve pending applications or supplemental applications***, and potentially civil and/or criminal penalties depending on the matter.

192. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Baluch certified that "[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "***[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company***."

193. The statements referenced in ¶¶189-192 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business

and operations, including that: (i) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iii) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate its commercial readiness; and (iv) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

194. On April 22, 2020, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, announcing it had completed the sale of $5.5 million of NOL tax benefits through the New Jersey Technology Business Tax Certificate Transfer Program ("4/22/20 Press Release").[107] In that press release, Defendant Baluch was quoted as stating, in relevant part "***[w]e have remained on***

[107] *CorMedix Completes Sale of $5.5 Million of NOL Tax Benefits through New Jersey Technology Business Tax Certificate Transfer Program*, GLOBENEWSWIRE (Apr. 22, 2020, 8:00 ET) ("4/22/20 Press Release"), https://www.globenewswire.com/news-release/2020/04/22/2019921/0/en/CorMedix-Completes-Sale-of-5-5-Million-of-NOL-Tax-Benefits-through-New-Jersey-Technology-Business-Tax-Certificate-Transfer-Program.html.

schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic."

195. The statement referenced in ¶194 was materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns to CorMedix regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

196. On May 11, 2020, the Company issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Inc.

Reports First Quarter 2020 ["1Q20"] Financial Results and Provides Business Update" ("5/11/20 Press Release").[108] That press release quoted Defendant Baluch as stating, in relevant part, that "[w]e have been working remotely since mid-March, a transition we have made with little disruption and as a result ***we are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020***."

197. The statement referenced in ¶196 was materially false and misleading and/or omitted material facts, including that: (i) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) likewise, the FDA had already raised concerns to CorMedix regarding the CMC information presented, including but not limited to, data sufficient to show that the labeled volume of the drug product could be consistently withdrawn from vials, despite existing in-process controls; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of DefenCath were adequate to preserve its identity, strength, quality and/or purity; (iv) therefore, the additional data CorMedix and its CMO were preparing to submit was

[108] *CorMedix Inc. Reports First Quarter 2020 Financial Results and Provides Business Update*, GLOBENEWSWIRE (May 11, 2020, 1610 ET) ("5/11/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/05/11/2031451/0/en/CorMedix-Inc-Reports-First-Quarter-2020-Financial-Results-and-Provides-Business-Update.html.

insufficient to demonstrate the CMO's commercial readiness; and (v) as a result, the DefenCath NDA submission lacked sufficient evidence and could not obtain FDA approval in the second half of 2020.

198. On July 8, 2020, during pre-market hours, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, announcing that it had completed its submission of the DefenCath NDA with the FDA for CRBSIs in patients with end-stage renal disease who are receiving hemodialysis via a central venous catheter ("7/8/20 Press Release").[109] That press release stated, in relevant part, that "***all of the modules for the Defencath™ [NDA] have been submitted*** to the [FDA]" and that "***there has been ongoing dialogue with FDA as it reviews the submitted modules***."

199. The 7/8/20 Press Release also quoted Defendant Baluch, who represented, in relevant part, that CorMedix was "very pleased to have ***completed the submission of the NDA, despite the limitations imposed by the COVID-19 pandemic, which delayed some required laboratory testing and our submission***."

200. The statements referenced in ¶¶198-199 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not

[109] 7.8.20 Press Release.

limited to, the process for filling the vials yielded inconsistent fill volume; (ii) the required laboratory testing was likely the result of the FDA's request to CorMedix for additional information, therefore, the delayed submission is more likely a result of the foregoing deficiencies than limitations imposed by the COVID-19 pandemic; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval in the second half of 2020.

201. On August 10, 2020, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting the Company's results for the second quarter of 2020 ("2Q20") and providing a business update (the "8/10/20 Press Release"). That press release represented, *inter alia*, that CorMedix had "***[c]ompleted the rolling submission and review of the [NDA] for Defencath to the FDA*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via catheter."

202. Additionally, the 8/10/20 Press Release quoted Defendant Baluch, who stated, in relevant part, that "[w]e were pleased to announce ***the completion of our rolling submission for Defencath last month*** and look forward to providing updates

on the acceptance for filing from FDA… We also are ***making necessary preparations for the launch of DefenCath in the U.S. hemodialysis market, following FDA approval***. We believe ***we have the team***, the focus, and a therapy that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

203. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting its financial and operating results for the quarter ended June 30, 2020, signed by Defendant Baluch.[110] The 2Q20 10-Q discussed the Company's DefenCath NDA submission with the FDA, stating, *inter alia*, that "[i]n March 2020, the Company began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently announced ***on July 8, 2020, that submission of all modules for the NDA was completed***" and that it "has not been informed of any delays by the FDA in the review of the NDA[.]"

204. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX certifications referenced in ¶192, *supra*, signed by Defendants Baluch and David.

205. The statements referenced in ¶¶201-204 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA's request for additional data reflected the existence of deficiencies at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (ii) despite

[110] CorMedix, Inc., Quarterly Report (Form 10-Q) (Aug. 10, 2020) ("2Q20 10-Q").

ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iii) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (iv) as a result, the DefenCath NDA could not obtain FDA approval.

206. On August 31, 2020, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, announcing the FDA's acceptance for filing and priority review of the DefenCath NDA, and setting a PDUFA date of February 28, 2021, for the completion of its review ("8/31/20 Press Release").[111] That press release stated that, "[t]he FDA had previously granted a ***rolling submission and review, which the Company completed at the end of June.***"

207. The 8/31/20 Press Release also quoted Defendant Mounts, who asserted, in relevant part, that "we look forward to ***continuing to work together [with the FDA] expeditiously to complete the review of the Defencath NDA*** to address an unmet medical need."

208. The statements referenced in ¶¶206-207 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business

[111] *CorMedix Inc. Announces FDA Acceptance for Filing and Priority Review of New Drug Application for Defencath,* GLOBENEWSWIRE (Aug. 31, 2020, 07:47 ET) ("8/31/20 Press Release"), https://www.globenewswire.com/en/news-release/2020/08/31/2086071/0/en/CorMedix-Inc-Announces-FDA-Acceptance-for-Filing-and-Priority-Review-of-New-Drug-Application-for-Defencath.html.

and operations, including that: (i) the FDA had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the module containing CMC information, submitted as part of the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

209. On November 5, 2020, CorMedix issued a press release, later filed as Exhibit 99.1 to a Form 8-K, signed by Defendant Baluch, reporting the Company's results for the third quarter of 2020 ("3Q20"), and providing a business update (the "11/5/20 Press Release"). That press release represented, in relevant part, that "***CorMedix continues its interactions with the FDA regarding the … NDA[] for Defencath™*** for the prevention of ... CRBSIs[] in patients undergoing hemodialysis via central venous catheter."

210. The 11/5/20 Press Release also quoted Defendant Baluch, who stated, in

relevant part, that "[w]e believe ***we have the team***, the focus, the resources, and a novel catheter lock solution that will meaningfully improve patient outcomes and are excited about the opportunities in front of us."

211. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting its financial and operating results for the quarter ended September 30, 2020 (the "3Q20 10-Q"). The 3Q20 10-Q stated, in relevant part, that:

> In March 2020, we began the modular submission process for the NDA for Defencath for the prevention of CRBSI in hemodialysis patients, and recently ***announced on July 8, 2020, that submission of all modules for the NDA was completed***. In August 2020, the FDA accepted for filing the Defencath NDA… ***The FDA noted that … it had not identified any potential review issues at this time…***

212. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications referenced in ¶192, *supra*, signed by Defendants Baluch and David.

213. The statements referenced in ¶¶209-212 were materially false and misleading because Defendants made material misstatements, as well as failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the FDA had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies– some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing

dialogue with the FDA and robust industry guidance, Defendants had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the DefenCath NDA reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

214. On November 18, 2020, CorMedix issued its 11/18/20 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing the FDA's decision that an advisory committee meeting for the DefenCath NDA was not needed.[112] That press release advised that "CorMedix has been notified that ***based on the [FDA]'s ongoing dialogue with the Company, discussion at an advisory committee is not needed, and it will continue to work on the application with CorMedix during the remainder of the review cycle***."

215. The 11/18/20 Press Release also quoted Defendant Baluch, who asserted that CorMedix and the FDA were working closely together on the DefenCath NDA, stating that "[w]e are very happy with ***the level of engagement between FDA and the CorMedix team during the NDA review process***."

216. Additionally, the 11/18/20 Press Release quoted Defendant Mounts, who likewise asserted that CorMedix and the FDA were working closely together on the DefenCath NDA, stating that "the ***tremendous effort of the CorMedix team has resulted in continuing progress with the FDA in the review of the NDA*** and that the

[112] 11/18/20 Press Release.

decision was made that ***no discussion with an advisory committee is needed***[,]" and that "[w]e intend to ***continue our effort and dialogue with the [FDA] to ensure that the priority review process can be completed expeditiously*** to address the unmet medical need…"

217. The statements referenced in ¶¶214-216 were materially false and misleading and/or omitted material facts, including that: (i) Defendants downplayed the true scope of their interactions with the FDA such that the agency had already raised concerns regarding existing manufacturing records submitted as part of the NDA, and as part of its records inspection, had requested additional documents from the CMO to support its commercial readiness; (ii) deficiencies–some of which were known to Defendants via an internal audit conducted in 2018–existed at the facility manufacturing DefenCath, including but not limited to, the process for filling the vials yielded inconsistent fill volume; (iii) despite ongoing dialogue with the FDA, CorMedix "team", including the Individual Defendants, had failed to ensure that the methods used in manufacturing and the controls used in maintaining the quality of its drug product met regulatory standards; (iv) the DefenCath NDA, reflected those deficiencies; and (v) as a result, the DefenCath NDA could not obtain FDA approval.

A. The Truth Slowly Leaks Out[113]

1. Partial Disclosure on March 1, 2021

218. On February 26, 2021, CorMedix received the First CRL, rejecting the DefenCath NDA due to manufacturing issues that either been previously communicated to the Company, or were within the custody or control of Defendants.

219. On March 1, 2021, pre-market, the Company issued a press release, later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, titled "CorMedix Receives Complete Response Letter from FDA for DefenCath™ Catheter Lock Solution[,]" "announc[ing] that the [FDA] cannot approve the [NDA] for DefenCath … in its present form." Specifically, CorMedix informed investors:

> **FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility.** FDA did not specify the issues and **CorMedix intends to work with the manufacturing facility to develop a plan for resolution** when FDA informs the facility of the specific concerns. When we are informed of the issues, we will schedule an investor conference call to provide an update on our expected timeline for resolution. **Additionally, FDA is requiring a manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications.** CorMedix expects to be able to complete this requirement expeditiously.
>
> **Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.** If an inspection is required, the FDA is currently facing a backlog due to the

[113] In this Section, the alleged false and/or misleading portions of the statements are both bolded and italicized. The alleged corrective disclosure portion of the statements are only bolded.

> pandemic and are actively working to define an approach for scheduling outstanding inspections once safe travel may resume. CorMedix will request a meeting with the FDA, which we estimate will occur by mid-April, to obtain agreement with the Agency on our proposed plan for resolution of the issues at our third-party manufacturing facility.

220. On this news, CorMedix's stock price fell $8.16 per share, or 54.4%, to close at $6.84 per share on March 3, 2021. As *Truist* analyst Lee explained, the First CRL "***c[a]me[] as a surprise as the product has already been in production and commercial in the EU, albeit at limited capacity.***" (Emphasis in original).[114]

221. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period, as a result of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies plaguing the manufacturers of DefenCath, relating to the facilities themselves and the manufacturing process. As a result, investors were misled into believing that the issues causing the First CRL were minor and would be resolved quickly, enabling the Company to resubmit the DefenCath NDA in the 2021 calendar year. Moreover, based on Defendants' consistent assurances that they were working closing with their manufacturers and the FDA, investors were misled into believing that the Company had the control of manufacturing and quality of its drug product that was necessary to meet regulatory standards.

222. Indeed, after speaking to "the mgmnt team on the [First] CRL" on March

[114] Joon Lee, M.D., Ph.D., Les Sulewski, *CRL Due To CMC Issues. No Deficiencies Related to Efficacy Or Safety of Defencath*, TRUIST SECURITIES (Mar. 1, 2021).

1, 2021, *Truist* analyst Lee of noted that the "40% selloff appears overdone" based on the "lack of fundamental issues with DefenCath itself."[115]

223. On March 9, 2021, CorMedix hosted its CRL Call, during which, Defendant Mounts stated, in relevant part:

> As I said, there were 6 facility deficiencies remaining at the conclusion of the assessment of the records request. ***Based on our discussions with the CMO, we believe these deficiencies can be resolved in the coming weeks***. For example, one deficiency results from the proposed future installation of new equipment, but it was apparently not clear to FDA that the equipment is unrelated to the manufacturer of DEFENCATH because FDA has requested details to assess the impact to production readiness for DEFENCATH.
>
> Three of the deficiencies involve activities associated with the vial filling line, in particular, the target filling volume. Additionally, a related approvability issue with the FDA's request communicated directly to CorMedix for a required ***manual extraction study to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.*** As we noted in the March 1 press release, there is an existing in-process control to demonstrate fill volume within specifications. ***We have submitted data to FDA to demonstrate performance with the specifications but we intend to conduct the requested manual extraction study and expect it to be completed in the next several weeks***. Another deficiency identifies concerns an airflow visualization study, and ***will likely necessitate repeating the study to demonstrate adequate dynamic conditions*** in the study, ***which we believe can be accomplished in the next several weeks.***
>
> The sixth deficiency requests documentation to support appropriate closing of deviations or nonconformances. ***We are working with the CMO to provide existing documentation to demonstrate that corrective actions are adequate to assure production controls are in place and to ensure standard operating procedures are consistent with actual practices and documentation is completed in a timely manner***.

[115] Joon Lee, M.D., Ph.D., Les Sulewski, *Selloff On CMC Issues Overdone. R BUY But PT To $30 (-$5) On Launch Delays*, TRUIST SECURITIES (Mar. 1, 2021).

224. In addition, during the CRL Call, Defendant Armstrong stated, in relevant part:

> Consistent with industry practice, we continued to work closely with the CMO via site visits and regular conference calls to prepare for an FDA inspection after submission of the NDA. We manufactured and validated 3 commercial scale drug product batches. ***All drug product made at the CMO for validation batches and subsequent batches met specifications. The drug product*** was put on accelerated and normal stability testing and ***continues to meet specifications.***

225. Defendant Baluch further added during the CRL Call, in relevant part, that "[w]e are working as fast as we can, in concert with the CMO, which is fully cooperating to develop and execute the plan. We believe ***we have within CorMedix and the CMO, the resources and capabilities to achieve successful resolution of the manufacturing deficiencies to the satisfaction of the FDA***."

226. Later during the CRL Call, *JMP* analyst Jason Nicholas Butler asked for "more color you can give on FDA's issues with the vial finishing lines? Anything you can tell us about whether these lines are used solely for DEFENCATH or other products? Or anything that's unique or different about these lines versus other fill/finish facilities? And then, just in terms of your overfill margins, is there anything you're doing different here? Or anything different to industry standard in terms of your overfill margins?"

227. Defendant Armstrong responded, in relevant part, "***[w]e are following the guidelines that are given, and we are following the guidelines on the overfill. And it's not different than we were doing before. We are within the guidelines***."

228. The statements referenced in ¶¶223-227 were materially false and misleading and/or omitted material facts, including that: (i) despite claims of "working with the CMO", Defendants had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved"; (iv) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (v) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; (vi) because the CMO's process for filling the vials was so flawed, it could only remedy deficiencies by changing its fill process to meet specifications; (vii) as a result, the CMO would need to conduct additional process qualification with subsequent validation data to support; and (viii) as a result of insufficient documentation and inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed.

229. Then, on March 30, 2021, CorMedix issued a press release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its 4Q20 results and providing a business update.[116] That press release continued to generally advise that the "FDA noted concerns at the third-party manufacturing facility after a review of records requested by FDA and provided by the manufacturing facility, and has requested a ***manual extraction study to demonstrate that the labeled volume can be consistently withdrawn from vials***" and "***CorMedix continues to work closely with our third-party manufacturing facility*** and is planning for a meeting with the FDA in mid-April to obtain agreement on the adequacy of our proposed plans for resolution of the deficiencies."

230. That same day, CorMedix filed an annual report on Form 10-K with the SEC, reporting its financial and operating results for the quarter and year ended December 31, 2020.[117] The 2020 10-K advised, *inter alia*:

> As we announced in March 2021, the FDA has informed us that it will not approve the NDA for DefenCath in its present form. The FDA noted concerns at the third-party manufacturing facility after a review of records requested by the FDA and provided by the manufacturing facility**.** ***We are working with the manufacturing facility to develop plans for resolution of the deficiencies***. Additionally, the FDA is requiring ***a manual extraction study to demonstrate that the labeled volume can be***

[116] *CorMedix Inc. Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update*, GLOBENEWSWIRE (March 30, 2021, 16:05 ET) ("3/30/21 Press Release"), https://www.globenewswire.com/news-release/2021/03/30/2201949/0/en/CorMedix-Inc-Reports-Fourth-Quarter-and-Full-Year-2020-Financial-Results-and-Provides-Business-Update.html.

[117] CorMedix, Inc., Annual Report (Form 10-K) (Mar. 30, 2021) ("2020 10-K").

> ***consistently withdrawn from the vials despite an existing in-process control to demonstrate fill volume within specifications.*** We expect to be able to complete this requirement expeditiously. Satisfactory resolution of these issues is required for approval of the DefenCath NDA by a pre-approval inspection and/or adequate manufacturing facility responses addressing these concerns.

231. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications referenced in ¶192 *supra*, signed by Defendants Baluch and David.

232. Later that same day, Defendants hosted the Company's 4Q20 Call at 4:30ET to discuss, among other things, its 4Q20 financial results. During that call, Defendant Baluch assured investors that "we remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified.***"

233. In addition, during the 4Q20 call, Defendant Mounts advised:

> I will start with the all-important timeline. The timeline we outlined on March 1 and reiterated on March 9 for a planned meeting with the FDA in mid-April remains on track based on the progress we have made. ***We have been working intensely with our third-party manufacturing facility to develop the proposed resolutions to the deficiencies.***
>
> ***There has been a strong collaborative effort to develop responses for each of the six deficiencies identified by FDA for the manufacturing facility.*** In addition, we have developed the protocol for ***the manual extraction study being required by FDA to demonstrate that the labeled volume of the drug product can be consistently withdrawn from vials.***
>
> I am pleased to announce that FDA has granted our request to meet with them to begin resolving the outstanding deficiencies. As we have previously stated, the purpose of the meeting with FDA is to obtain agreement with the agency on the adequacy of our proposed plans for resolution of the deficiencies. Our contract manufacturing organization will join us in the meeting with FDA.
>
> As we planned, the meeting will occur in mid-April, and we will

> provide an update on our progress and timeline for resolution of the deficiencies after the meeting with FDA. Our goal is to ensure that FDA can conclude that the manufacturing facility is ready to support commercial operation for DEFENCATH without the need for an on- site inspection.

234. On the same call, regarding CorMedix's anticipated meeting with the FDA to discuss the DefenCath NDA, *JMP* analyst Jason Butler asked whether "you will actually have any of the work requested by FDA completed by the meeting, either in terms of documentation protocols, or the vial fill volume study or airflow visualization studies that they asked for," and whether "you've actually completed any, or have any new data to take to the meeting?" In response, Defendant Mounts assured investors, "yes, we obviously were involved in developing the proposed responses"; that "[s]ome of those proposed responses involve existing documentation"; that "***we ma[d]e sure that – -- where we could, we provided information that was responsive to the deficiency***"; and that "***there is new information there for them to review for some of the responses***."

235. The statements referenced in ¶¶229-234 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) despite claims of "work[ing] closely" and "intensely" with the CMO, CorMedix's "team", including the Individual Defendants, had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing

documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved"; (iv) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (v) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; (vi) because the CMO's process for filling the vials was so flawed, it could only remedy deficiencies by changing its fill process to meet specifications; (vii) as a result, the CMO would need to conduct additional process qualification with subsequent validation data to support; and (viii) as a result of insufficient documentation and inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed.

2. Partial Disclosure on April 14, 2021

236. On April 14, 2021, pre-market, CorMedix issued its 4/14/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, announcing "that it has met with the [FDA] to discuss proposed resolutions for the deficiencies identified in the [First CRL] to CorMedix and the Post-Application Action

Letter received by the third-party manufacturer (CMO) from FDA for the [NDA] for DefenCath." Specifically, that press release disclosed, in relevant part, that "**[a]ddressing FDA's concerns regarding the qualification of the filing operation may necessitate adjustments in the process and generation of additional data on operating parameters for manufacture of DefenCath.**"

237. On this news, CorMedix's stock price fell $1.72 per share, or 18.36%, to close at $7.65 per share on April 15, 2021.

238. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period as a result of Defendants' continued misrepresentations and omissions regarding the true scope of the existing deficiencies at the facility manufacturing DefenCath and with the manufacturing process itself. Moreover, Defendants made materially false and misleading statements and/or failed to disclose material facts relating to the amount of time it would take the CMO to rectify these deficiencies.

239. First, after assuring investors that "[r]epresentatives from both CorMedix and the CMO participated in the meeting with FDA to ensure that there is alignment on addressing the [FDA]'s concerns[,]" the 4/14/21 Press Release stated, in relevant part, that:

> ***CorMedix and the CMO are currently evaluating available data to determine if additional process qualification will be needed with subsequent validation to address these issues.***
>
> The FDA stated that the review timeline would be determined when

> the NDA resubmission is received and that it expected all corrections to facility deficiencies to be complete at the time of resubmission so that all corrective actions may be verified during an on-site evaluation in the next review cycle, if the FDA determines it will do an onsite evaluation. ***CorMedix and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA.
>
> ***CorMedix will provide updates on the timeline as resolution of the deficiencies proceeds.***

240. Next, CorMedix's Corporate Presentation, issued on April 14, 2021, provided a "Manufacturing Overview: Supply Chain Substantially Completed; Launch Quantities in Production", stating, in relevant part, that CorMedix had "***[s]uccessfully concluded technical transfer and validation of the drug product manufacturing process***, which has enabled production at 2 different manufacturing locations[,]" and that "***[l]aunch quantities are already in production***[.]"[118]

241. The statements referenced in ¶¶239-240 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) despite claims of "work[ing] closely" with the CMO, Defendants had failed to ensure processes were in place to assure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing

[118] *Corporate Presentation*, CORMEDIX, INC. (Apr. 14, 2021) ("April 2021 Presentation") https://www.cormedix.com/wp-content/uploads/2021/04/CorMedix_Corporate-Presentation_4-14-21-v3.pdf.

and quality controls met cGMP standards; (iii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved"; (iv) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (v) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; (vi) because the CMO's process for filling the vials was so flawed, it could only remedy deficiencies by changing its fill process to meet specifications; (vii) as a result, the CMO would need to conduct additional process qualification with subsequent validation data to support; and (viii) as a result of insufficient documentation and inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed.

3. Partial Disclosure on May 13, 2021

242. On May 13, 2021, during post-market hours, CorMedix issued its 5/13/21 Press Release, which was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its results for the first quarter of 2021 ("1Q21") and providing a business update. That press release revealed, in relevant part, that "**[b]ased on [CorMedix's] analyses, we have concluded that additional process qualification**

will be needed with subsequent validation to address the deficiencies identified by FDA."

243. Later that same day, also during post-market hours, Defendants hosted a conference call with investors and analysts to discuss, among other things, CorMedix's progress with the DefenCath NDA.[119] During the 1Q21 Call, Defendant Mounts reiterated this disclosure, providing, in relevant part, that:

> As we have explained previously, the major focus of FDA's concerns was on the qualification of the filling operation and CorMedix and the CMO have been evaluating available data to assess the need for adjustments in the manufacturing process and generation of additional data on operating parameters for manufacture of DEFENCATH.
>
> Based on our analysis, we have concluded that additional process qualification will be needed with subsequent validation to address the deficiencies identified by FDA. As a result, ***our current plan is to be able to resubmit the [DEFENCATH] NDA in [4Q21]***.

244. Then, during the Q&A Session of the 1Q21 Call, *JMP* analyst Jason Butler asked "in terms of the additional in process qualification work, have you already agreed with your CMO what the plan is there? And what needs to be done? And is there any granularity you can give us in terms of timeline[] to complete that work?" To which, Defendant Mounts responded:

> Yes, we have agreed with the CMO on the plan to go forward to resolve the deficiencies and generate the additional data required by FDA. As we have said, the **FDA has focused on the in-process controls and has**

[119] *CorMedix, Inc. (CRMD) CEO Khoso Baluch on Q1 2021 Results - Earnings Call Transcript*, SEEKING ALPHA (May 13, 2021, 04:30 PM ET) ("1Q21 Call"), https://seekingalpha.com/article/4428474-cormedix-inc-crmd-ceo-khoso-baluch-on-q1-2021-results-earnings-call-transcript.

> **requested some additional data on the process qualification**. And as a result of that, we will be **required to manufacture the validation batches** to fulfill the request from the agency.

245. Needham analyst Chad Messer pressed for clearer details on deficiencies identified with regards to the CMO's filling operations, as well as the Company's anticipated timeline for achieving the resolution of them prior to the 4Q21 NDA submission.

246. When specifically pressed for these additional details, Defendant Mounts disclosed, in relevant part:

> [I]t is a complicated process and [ ] it is not simple, and **like all technical work, needs to be conducted with precision and is subject to issues when something can go wrong.** It is highly sophisticated equipment. **And so there are times when there may be unexpected results obtained.**
>
> FDA's concern as they express[ed] to us during our meetings with them focused on the filling operation, which is the process by which DEFENCATH is during a sterile procedure loaded into the vials and then the vials are kept.
>
> **They expect us to generate sufficient data to demonstrate that, that process is a controlled process and is consistent with the agency's requirements for good manufacturing practice.** So clearly, sterility is a very important part of that process, but also **the accuracy in making sure the right volume of DEFENCATH is loaded into the vials.** And we are talking about thousands of vials during the manufacturing run.
>
> So as I said, it is a complicated process and technically very involved and involves a generation of a lot of data to make sure that the process itself is using the jargon qualified, which means all the equipment has been qualified for the intended use and every step in the manufacturing process has been qualified.
>
> And that everything works as it is intended to produce the product that has to meet its specifications**.** So they are very detailed requirements

> on a chemical basis as well on a performance basis that is required for the product.
>
> And so that **process needs to be very robust, needs to be reproducible.** And the burden is on the manufacturer to demonstrate that the facility can do that process reducibly and generate the required product for commercial distribution.

247. On this news, CorMedix's stock price fell $1.51 per share, or 19.97%, to close at $6.05 per share on May 14, 2021.

248. Despite this decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misrepresentations and omissions regarding the true scope of the deficiencies at the facility manufacturing DefenCath and with the manufacturing process itself. Moreover, Defendants made materially false and misleading statements and/or failed to disclose material facts relating to the amount of time it would take the CMO to try and rectify these deficiencies.

249. For example, the 5/13/21 Press Release stated, in relevant part, that "***CorMedix successfully completed the agreed upon protocol for the manual extraction study identified in the Complete Response Letter*** that FDA is requiring ***as confirmation of in-process controls to demonstrate that the labeled volume can be consistently withdrawn from the vials***."

250. In addition, Defendant Baluch is quoted in the 5/13/21 Press Release as stating, in relevant part, "As we continue to work through the items required by FDA for resubmission of the NDA, we remain confident in our efforts[,]" and "[w]e believe

we have the right team and resources to accomplish this as we advance DefenCath through the regulatory approval process."

251. Similarly, during the 1Q21 Call, Defendant Baluch stated, in relevant part, that "[w]e remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiency***."

252. Also, during the 1Q21 Call, Defendant Mounts went on to add, in relevant part, that:

> As we previously discussed, the [] CRL, sent to CorMedix by the FDA required ***a manual extraction study to demonstrate that the labeled volume of DEFENCATH can be consistently withdrawn from the vials to confirm the manufacturing in process controls.***
>
> I am pleased to report that the study has been completed successfully. As noted by [Defendant Baluch], we announced after the meeting with FDA that we had an agreed-upon protocol that has now been executed.
>
> The data clearly demonstrate consistent withdrawal of the labeled volume from the vials. ***The CorMedix CMC and regulatory teams continue to focus our efforts on resolving the deficiencies [sent] to the [] CMO***, in the post application action letter.

253. That same day, CorMedix filed a quarterly report on Form 10-Q with the SEC, reporting its financial and operating results for the quarter ended March 31, 2021.[120] The 1Q21 10-Q further assured investors that "***[t]he Company and the CMO continue to work closely to ensure that the identified deficiencies are resolved*** prior to resubmission of the DefenCath NDA."

[120] CorMedix, Inc., Quarterly Report (Form 10-Q) (May 13, 2021) ("1Q21 10-Q").

254. Appended as exhibits to the 1Q21 10-Q were substantively the same SOX certifications referenced in ¶192, *supra*, signed by Defendants Baluch and David.

255. The statements referenced in ¶¶249-254 were materially false and misleading and/or failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) despite claims of "work[ing] closely" with the CMO, Defendants had failed to ensure the methods used in manufacturing and the controls used to maintain the quality of its drug product were adequate to preserve DefenCath's identity, strength, quality and/or purity; (ii) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (iii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved" (iv) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (v) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through the production of additional data alone, including the manual extraction study; and (vi) as a result of insufficient documentation and inadequate processes relating to filling the vial, the CMO's ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed and the Company would not resubmit its NDA in 4Q21.

256. Then, on August 12, 2021, CorMedix issued its 8/12/21 Press Release, that was later filed as Exhibit 99.1 to a Form 8-K signed by Defendant Baluch, reporting its 2Q21 results and providing a business update. That press release stated, in relevant part, that "CorMedix remains focused in its efforts to resolve the deficiencies sent to the third-party manufacturer in the Post-Application Action Letter and ***remains on schedule to re-submit the DefenCath™ New Drug Application in [4Q21]***."

257. Later that day, Defendants hosted the Company's 2Q21 Call with investors and analysts at 4:30 ET to discuss, among other things, its progress with the addressing the deficiencies identified by the FDA and its work to resubmit the DefenCath NDA in 4Q21. On that call, Defendant Baluch stated, in relevant part, during his opening remarks:

> During the last earnings call on May 13, we provided an update on the progress that CorMedix has made to date on addressing the deficiencies identified by the FDA as the third-party manufacturing facility. The work has continued and we are reiterating that ***at present, we are on schedule to be able to resubmit the CorMedix NDA in quarter 4, 2021.***
>
> * * *
>
> We are also balancing our preparation for launching DEFENCATH while limiting our cash burn so that ***financially we have the resources required to efficiently bring DEFENCATH to patients in the U.S. market when FDA approval is received.***
>
> * * *
>
> To summarize, ***we continue to focus our effort expeditiously resolving the third-party manufacturing deficiencies with a plan to resubmit in quarter 4, 2021.*** We are carefully balancing our cash burn, while preparing for the launch of DEFENCATH ***once we have approval of the NDA by the FDA***.

* * *

We remain confident that ***we have the right team and appropriate resources in place to resolve the third-party manufacturing deficiencies that have been identified*** and bring DEFENCATH to hemodialysis patients in the U.S.

258. In addition, Defendant Mounts stated, in relevant part, that:

I will start by assuring you that ***we remain on schedule to resubmit the new drug application or NDA in [4Q21]***. We have continued to work diligently to resolve deficiencies identified by FDA as a third-party manufacturing facility or CMO.

As I have explained previously, we have ***successfully completed the manual extraction study required by FDA*** and the Complete Response Letter or CRL sent by the FDA to CorMedix. ***We have demonstrated that the labeled volume of DEFENCATH can be consistently withdrawn from the v[ials].***

Also, as we have explained previously, resolution of the deficiencies at the manufacturing facility identified in the post-application action letter sent to the CMO has required additional process qualification with subsequent validations for the vial filling process. The process qualification and validation are done by the manufacturing facility and ***we are working closely with them and CMC consultants engaged by CorMedix to ensure that we are addressing FDA concerns appropriately***.

The deficiencies communicated to the CMO by FDA need to be satisfactorily addressed for approval of the DEFENCATH NDA. ***The CMC and regulatory teams of CorMedix are working collaboratively with the CMO to ensure the generation of the required data and documentation to resubmit the NDA in [4Q21]***.

259. During the Q&A Session of the 2Q21 Call, *Truist* analyst Joon Lee asked, "[r]egarding the process qualification of vials and the vial filling process, and the manual extraction studies. Did those require production of new batches of DEFENCATH? And if so, will you need stability data from those new batches before you can submit the NDA or during the process of NDA [Indiscernible]?" In response,

Defendant Mounts stated:

> [A]s I've explained, we need to do some, as you said, process qualification. And then you need to validate that by generating additional batches and part of the program for any manufactured batches that are intended for commercial use, or to put those batches into a stability program, and to generate stability data to demonstrate in fact that the product is stable and continues to meet specifications.
>
> ***We have an abundance of data on stability of other batches that have been produced. And so we expect to be able to show consistency.***

260. The statements referenced in ¶¶256-259 were materially false and misleading because the Company had neither "successfully" demonstrated fill consistency nor had "an abundance of data on stability of other batches" that met FDA standards. In addition, they failed to disclose material adverse facts about CorMedix's business and operations, including that: (i) the CMO's existing documentation was insufficient to show its methods of manufacturing and quality controls met cGMP standards; (ii) as a result, it would be necessary for the CMO to collect additional data, including but not limited to, an airflow visualization study, in order to achieve resolution of the identified deficiencies; (iii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved"; (iv) the CMO's process for filling the vials was so flawed that the related deficiencies could not be resolved through CorMedix's production of additional data alone, *i.e.*, the manual extraction study; (v) at all relevant times, the CMO manufactured multiple different drug products using the same manufacturing lines, yet, despite claims of

"work[ing] closely" with the CMO, Defendants failed to ensure that the CMO's protocols relating to changeover of manufacturing lines and its processes for visual inspection of the drug product met cGMP standards; (vi) as a result of deficient changeover protocols and visual inspections processes, the CMO manufactured contaminated vials; and (vii) as a result of insufficient documentation and the foregoing deficiencies at the CMO's manufacturing facilities, its ability to obtain the necessary data to assure the FDA that the identified deficiencies had been resolved would be delayed and CorMedix could not resubmit its NDA in 4Q21.

4. Partial Disclosure on September 7, 2021

261. Then, on September 7, 2021 at 8:30 AM ET, the Company issued its 9/7/21 Press Release, disclosing that "**CorMedix has encountered delays at its third-party [CMO]**" relating to "issues that are unrelated to DefenCath manufacturing activities" and that "**the timeline for CorMedix and the CMO to address deficiencies** at the facility that are required for resubmission of the DefenCath NDA **is uncertain at this time**."

262. On this news, CorMedix's stock price fell $1.77 per share, or 27.40%, to close at $4.69 per share on September 9, 2021.

263. Analysts attributed the Company's stock price decline to the now uncertain resubmission deadline. As a September 7, 2021 article by the Motley Fool titled "Why CorMedix Stock Is Getting Crushed Today" noted, the Company's "stock

was getting crushed on Tuesday, with shares down 23.7% as of 11 a.m. EDT … after the company announced that it 'has encountered delays at its third-party contract manufacturer.' These delays will push back CorMedix's refiling for [FDA] approval of its DefenCath antibacterial and antifungal catheter lock solution by an undetermined amount of time."[121]

264. While industry analysts following CorMedix also understood its disclosure to mean that the "**CMO delay brings uncertainty to Defencath NDA resubmission timelines**," they were still bullish on the Company because they were able to "**confirm[] with management** that CorMedix continues to maintain a very good working relationship with its CMO and there is still full agreement on the work needed to complete the NDA resubmission."[122]

265. Thus, despite the decline in the Company's stock price, CorMedix securities continued to trade at artificially inflated prices throughout the rest of the Class Period as a result of Defendants' statements. Specifically, they misrepresented their CMO's ability to pass an FDA on-site inspection while concealing ongoing manufacturing issues at the facility that was manufacturing DefenCath, and

[121] 9/7/21 Motley Fool; *see also* 9/7/21 SEEKING ALPHA ("CorMedix's stock price "slump[ed] 20.6% premarket after the company provided an update with respect to its resubmission timeline for the DefenCath [NDA]")

[122] Jason N. Butler, PhD, Roy Buchanan, PhD, *Defencath Announcement Increases Timing Uncertainty, but Fundamental Impact Unlikely*, JMP SECURITIES LLC (Sep. 7, 2021).

misrepresented potential supply chain risks while concealing that serious risks had materialized due to the FDA's concerns about manufacturing deficiencies observed during an on-site inspection of their heparin supplier's facility.

266. On February 28, 2022, CorMedix issued a press release announcing its resubmission of the DefenCath NDA addressing the manufacturing deficiencies identified by the FDA a year prior.[123] That press release quoted Defendant Mounts as stating, in relevant part, that "***we and the manufacturer have adequately addressed the concerns the [FDA] identified in the CRL and PAAL***."

267. On March 28, 2022, CorMedix issued a press release announcing FDA acceptance of the DefenCath NDA resubmission, explaining that it was considered a Class 2 response warranting a re-inspection of the Company's CMO's facilities.[124] That press release quoted Defendant Mounts as stating, in relevant part, that "***both CorMedix and our contract manufacturer have adequately addressed the concerns the Agency identified during the review of the original NDA***..."

268. The next day, on March 29, 2022, CorMedix hosted a conference call with investors and analysts at 4:30 ET to discuss, among other things, the financial results for the fourth quarter 2021.[125] During her opening remarks, Defendant Mounts stated that "***CorMedix and the [CMO] have adequately addressed the concerns***

[123] 2/28/22 Press Release.

[124] 3/28/22 Press Release.

[125] 4Q21 Call.

identified by FDA....”

269. The statements referenced in ¶¶266-268 were materially false and misleading because (i) the CorMedix and its CMO **had not** “adequately addressed the concerns identified by the FDA”; (ii) CorMedix lacked evidence of “satisfactory resolution of [the] objectionable conditions” that the FDA had already told Defendants was “required … before this application may be approved”; and (iii) failed to disclose material adverse facts about CorMedix’s business and operations, including that it had not ensured its CMO complied, or even had sufficient knowledge and/or understanding to comply, with cGMP standards.

270. Defendant Mounts further confirmed that “***[w]e are committed to providing updates to investors as appropriate*** over the coming months during the review process.”

271. The statement referenced in ¶270 was materially false and misleading because Defendants made material misstatements, as well as failed to disclose material adverse facts about CorMedix’s business and operations, including that (i) CorMedix had not ensured its CMO complied, or even had sufficient knowledge and/or understanding to comply, with cGMP standards; (ii) CorMedix lacked evidence of “satisfactory resolution of [the] objectionable conditions” that the FDA had already told Defendants was “required … before this application may be approved”; (iii) the Company was not “committed to providing updates to investors” and in fact, had hid

the most damaging and important information from investors; and (iv) that the FDA had already observed manufacturing deficiencies at the third-party facility supplying the key active ingredient heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA.

272. In addition, Defendant Mounts stated that "it is important to anticipate ***potential supply chain challenges*** and ensure multiple sources are in place to provide adequate inventory."

273. The statement referenced in ¶272 was materially false and misleading because it (i) omitted that Defendants had never "ensure[d] multiple sources [were] in place to provide adequate inventory" and (ii) failed to disclose material adverse facts about CorMedix's business and operations, including that the FDA had already observed manufacturing deficiencies at the third-party facility supplying the key active ingredient heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA. Thus, the risk of "potential supply chain challenges" had already materialized, unbeknownst to investors. And yet Defendant Mounts said nothing about the manufacturing issues at the Company's heparin supplier's facility.

274. On May 12, 2022, CorMedix hosted a conference call with investors and

analysts at 4:30 ET to discuss, among other things, the financial results for the first quarter 2022.[126] During his opening remarks on that call, Defendant Todisco stated, in relevant part "***any FDA inspection of our CMO will assess the commercial readiness of the facility and manufacturing operations beyond those specific to DefenCath***."

275. The statement referenced in ¶274 was materially false and misleading because (i) the FDA had expressly told CorMedix that it had concerns about its CMO and fill process that were "specific to DefenCath"; and (ii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved" making operational concerns beyond DefenCath a moot point.

276. In addition, Defendant Todisco noted that "from a supply chain standpoint, ***we're also continuing initiatives to dual source key components and active ingredients in order to de-risk … potential governmental regulatory actions at any key supplier***."

277. Later during the 1Q22 Call, Needham analyst Rohit Bhasin followed up asking about "what kind of preparations are you guys making in terms of launch in terms of … manufacturing supply ahead of time?" Defendant Todisco responded:

> On the launch prep side, when – ***in terms of activities that we are currently undertaking, we are doing right now all the typical prelaunch planning***. We are building out our commercial plan, building out our core messaging, doing our pricing studies, building our staffing plans. But most

[126] 1Q22 Call.

> importantly, we are engaging those reimbursement activities and engaging key stakeholders to work with CMS, and we see that as one of the most critical components of our launch strategy.

278. The statements referenced in ¶¶276-277 were materially false and misleading because Defendants had not "de-risk[ed]" "governmental regulatory actions at any key supplier," and the statements failed to disclose material adverse facts about CorMedix's business and operations, including that the FDA had already observed manufacturing deficiencies at the third-party facility supplying the key active ingredient heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA. Thus, the risk of "potential governmental regulatory actions at any key supplier" had already materialized, unbeknownst to investors. And yet Defendant Todisco said nothing about the manufacturing issues at the Company's heparin supplier's facility – even when specifically asked about "manufacturing supply."

279. On June 15, 2022, Defendant Todisco presented at the JMP Securities Life Sciences Conference to discuss, among other things, the "attractive investment opportunity" in CorMedix and DefenCath.[127] During the presentation, Todisco was told that investors "are focused on the manufacturing inspection process" and was asked "[i]s everything there moving forward and still gives you confidence that that can be

[127] *JMP* Transcript.

completed in time to enable an approval later this quarter?" In response, Todisco stated in relevant part:

> ***So from everything that we can see***, I'm optimistic that everything is moving in the right direction.
>
> * * *
>
> ***[T]he big obstacle does appear to be the FDA's inspection at the site.*** … As any FDA inspection does, I expect there will be observations that have to be responded to. And we are going to work closely with our CMO for any observations that are related to DefenCath.
>
> I think that one of the key variables, though, is that ***this is an inspection of facility that is larger than just the manufacturing operations related to DefenCath.*** So to the extent that there are any observations that don't involve our product, we may not have the ability to work with our CMO in those responses or have full visibility.
>
> But I believe that our contract manufacturer is a reputable -- highly reputable European manufacturer. I think ***they're going to take all care to work diligently through any observations and work with the FDA on, if necessary, improving any compliance concerns FDA could raise***.

280. The statements referenced in ¶279 were materially false and misleading because (i) "everything [Defendants] could see" did not actually indicate that things were "moving in the right direction," including the fact that the FDA was still criticizing CorMedix's manufacturing process; (ii) the statements failed to disclose material adverse facts about CorMedix's business and operations, including that CorMedix had not ensured that its CMO complied, or even had sufficient knowledge and/or understanding to comply, with cGMP standards; and (iii) CorMedix lacked evidence of "satisfactory resolution of [the] objectionable conditions" that the FDA had already told Defendants was "required … before this application may be approved." Further, "everything that we can see" included that the FDA had observed

manufacturing deficiencies at the third-party facility supplying heparin for CorMedix which warranted the issuance of a Form 483 on February 4, 2022 and requests for corrective actions – adding high risk to the FDA approving the second DefenCath NDA.

B. The Truth Fully Emerges

281. After markets closed on August 8, 2022, CorMedix admitted that manufacturing issues at its CMO still existed through its announcement of yet another CRL "from the FDA stating that the DefenCath NDA cannot be approved until deficiencies recently conveyed to the [CMO] and the supplier of the [API] heparin during inspections are resolved to the satisfaction of FDA."[128] Despite deficiencies in the manufacturing of another drug at the CMO's facility impacting FDA approval of DefenCath, CorMedix again failed to sufficiently prepare for "the FDA conduct[ing] a recent inspection unrelated to DefenCath at the facility of the company's heparin supplier, which culminated in the API supplier receiving a warning letter as a result of manufacturing deficiencies for a non-heparin API." As a result, "by way of the CRL, the FDA has now informed the company that satisfactory resolution of these deficiencies will be required before the DefenCath NDA may be approved."

282. On this news, CorMedix's stock price fell $4.32 per share, or 57.45%, to close at $3.20 per share on August 9, 2022.

[128] 8/8/22 Press Release.

283. As SA News Editor Anuron Mitra noted on August 8, 2022, CorMedix's "new drug application for its antibacterial and antifungal solution DefenCath had been rejected by the U.S. FDA for a second time, sending its shares plunging 60.1% to $3 after hours."[129]

284. Analysts following the Company understood from its August 8, 2022 disclosure that manufacturing deficiencies continued to be the issue:

- "CorMedix disclosed receipt of a Complete Response Letter for DefenCath, solely noting ***outstanding*** manufacturing-related deficiencies."[130]
- "**CorMedix Inc. (CRMD)** CMC Issues Strike Again…"[131]

285. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

VI. LOSS CAUSATION

286. The false and misleading misrepresentations and material omissions, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class members he represents.

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[129] *FDA again rejects CorMedix's application for lead candidate DefenCath, shares sink ~60*, SEEKINGALPHA, (Aug. 8, 2022), https://seekingalpha.com/news/3869456-fda-again-rejects-cormedixs-application-for-lead-candidate-defencath-shares-sink-60.

[130] Jason N. Butler, PhD, Roy Buchanan, PhD, *More Manufacturing Speedbumps but Readily Addressable, In Our View*, JMP SECURITIES LLC (Aug. 9, 2022).

[131] Joon Lee, M.D., Ph.D., Les Sulewski, *CMC Issues Strike Again. But We Think They're Remediable In Short Period.* TRUIST SECURITIES, INC (Aug. 8, 2022).

287. During the Class Period, as detailed herein, Plaintiff and other Class members purchased CorMedix securities at artificially inflated prices and were damaged thereby. The price of CorMedix securities declined significantly when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were disseminated and publicly revealed.

288. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of CorMedix securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make the statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about CorMedix's business, operations, and prospects, as alleged herein.

289. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. Defendants made or caused to be made materially false and/or misleading statements about CorMedix's business, operations and future prospects. These material misstatements and/or omissions had the cause and effect of creating in the market a false positive assessment of the Company and its business and operational performance

and related well-being, thus causing its securities to be overvalued and the price of its securities to be artificially inflated at all relevant times. Defendants' materially false and/or misleading statements, as alleged herein, resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was partially revealed March 1, 2021, April 14, 2021, May 13, 2021, September 7, 2021, and then fully on August 8, 2022, causing the trading price of CorMedix securities to materially decline and removing the previously embedded artificial inflation.

290. By the commencement of this action, CorMedix's stock price closed at $6.42 per share on July 22, 2021, representing a 26% decline from the average $8.69 per share sold by the end of 2020 and a 42% decline from the average $11.10 per share sold in the six months ended June 30, 2021. On October 10, 2022, CorMedix securities closed at $2.85 per share, representing a 25% decline from the average $3.78 per share sold in the six months ended June 30, 2022.

VII. NO SAFE HARBOR

291. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as

"forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

292. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of CorMedix who knew that the statement was false and/or misleading when made.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

293. Given the substantial importance of FDA approval for DefenCath to the Company's financial performance, there is no doubt that Defendants had processes and procedures in place to immediately be made aware of any concerns raised by the FDA regarding meeting CMC standards at any facility manufacturing DefenCath or its API heparin. If Defendants lacked such processes and procedures, Defendants were reckless in not establishing them, and in not informing investors that they lacked such crucial controls.

294. The Individual Defendants possessed the requisite scienter as they had the power and authority to control the contents of CorMedix's SEC filings, press

releases, and other market communications. They were provided with copies of CorMedix's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with CorMedix, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

295. Likewise, as alleged herein, Defendants acted with scienter in that they knew the public documents and statements disseminated or issued in the name of the Company were materially false and misleading; knew that such statements or documents would be disseminated or issued to the investing public; and knowingly and substantially participated or acquiesced in disseminating or issuing of such statements or documents and in actions intended to manipulate the market price of CorMedix securities as primary violations of the securities laws.

296. The allegations herein also establish a strong inference that CorMedix as an entity acted with corporate scienter throughout the Class Period. Its officers, management, and agents, including, but not limited to, the Individual Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth

herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the concerns raised by the FDA from the investing public. Indeed, the FDA would have only communicated about those CMC issues with senior individuals at CorMedix who were in a position to establish its scienter. By concealing these material facts from investors, CorMedix maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

297. Moreover, given the extensive communications that the Individual Defendants had with analysts and investors, including Plaintiff, and the detail of their representations regarding their attention to detail and review of CMC standards, they each made themselves aware of the Company's and FDA's actual (but then-undisclosed) findings with respect to the CMC data presented or had no factual basis to make such specific quantitative statements. In either event, the Individual Defendants were at least reckless with respect to the truth, and their scienter is imputable to the Company.

IX. CLASS ACTION ALLEGATIONS

298. Plaintiff brings this action as a class action pursuant to Rules 23(a) and (b)(3) on behalf of all persons and entities who purchased or otherwise acquired

CorMedix securities between October 16, 2019 and August 8, 2022, inclusive (the "Class Period"). Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

299. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, CorMedix securities were actively traded on the NASDAQ and NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by CorMedix or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

300. Plaintiff's claims are typical of the claims of the Class members as all members of the Class are similarly affected by Defendants' wrongful conduct, in violation of federal securities law, complained of herein.

301. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

302. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members. Among the questions of law and fact common to the Class are:

- whether federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of the Company;
- whether the Individual Defendants caused CorMedix to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of the Company's securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

303. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation makes it impossible for them to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

304. Plaintiff and the other members of the Class will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that, *inter alia*: (a) Defendants made public misrepresentations or failed to disclose material facts;

(b) the omissions and misrepresentations were material; (c) the Company's securities traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and (e) Plaintiff and the other members of the Class purchased CorMedix securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

305. At all relevant times, the market for CorMedix securities was efficient for the following reasons, among others: (a) CorMedix securities met the listing requirements for, and were listed and actively traded on the NASDAQ and the NYSE, highly efficient markets; (b) during the Class Period, CorMedix shares were actively traded, supporting a strong presumption of efficiency; (c) CorMedix issued public reports with the SEC; (d) CorMedix regularly communicated with public investors, including via regular disseminations of press releases on major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; (e) CorMedix was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force, certain customers of their respective brokerage firms, and were publicly available; and (f) unexpected material news about CorMedix was rapidly reflected in and incorporated into the price of its securities during the Class Period.

306. Because CorMedix is a publicly traded company, Defendants knew,

understood and had reason to expect that: (1) their misstatements would artificially inflate the price of CorMedix securities; (2) investors would rely on the price of CorMedix common stock as reflecting accurate information known to CorMedix and its executives; and (3) their misstatements and omissions would induce Plaintiff and the other members of the Class to purchase CorMedix securities during the Class Period.

307. As a result of the foregoing, the market for CorMedix's securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in CorMedix's share price. Under these circumstances, all purchasers of CorMedix's securities during the Class Period suffered similar injury through their purchase of CorMedix's securities at artificially inflated prices and a presumption of reliance applies.

308. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded in Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding CorMedix's business, operations, and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable

investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

COUNT I
Violations of §10(b) of the Exchange Act and Rule 10b-5
(Against All Defendants)

309. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

310. This Count is asserted against Defendants and is based upon §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder.

311. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of CorMedix securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire CorMedix securities and options at artificially inflated

prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants took the actions set forth herein.

312. Pursuant to the above plan, scheme, conspiracy and course of conduct, each Individual Defendant named herein participated directly or indirectly in preparing and/or issuing quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for CorMedix securities. Such reports, filings, press releases and other statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about CorMedix's finances and business prospects.

313. By virtue of their positions at CorMedix, the Individual Defendants had actual knowledge of the material misstatements and omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Individual Defendants.

314. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Defendants named herein knew or recklessly disregarded that material facts were being misrepresented or omitted as

described above.

315. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within their knowledge and control. As the senior managers and/or directors of CorMedix, the Individual Defendants had knowledge of the details of the Company's internal affairs.

316. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of CorMedix. As officers and/or directors of a publicly held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to CorMedix's business, operations, prospects, and future financial condition.

317. As a result of the dissemination of false and misleading public reports, releases and statements described herein, the market price of CorMedix securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning CorMedix's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired CorMedix securities at artificially inflated prices, relying upon the price of the securities, the integrity of the market for the securities, and/or upon statements disseminated by Defendants, and were damaged thereby.

318. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired them at the inflated prices that were paid, or at all. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of CorMedix securities was substantially lower than the prices paid. The market price of CorMedix securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and other Class members.

319. By reason of the conduct alleged herein, Defendants, knowingly or recklessly, directly, or indirectly, violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

320. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of §20(a) of the Exchange Act
(Against the Individual Defendants)

321. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

322. During the Class Period, the Individual Defendants participated in the operation and management of CorMedix, and conducted and participated, directly and indirectly, in the conduct of CorMedix's business affairs. Because of their senior

positions, they knew the adverse non-public information about CorMedix's misstatement of income and expenses and false financial statements. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to CorMedix's financial condition and results of operations, and to correct promptly any public statements issued by CorMedix which had become materially false or misleading.

323. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which CorMedix disseminated in the marketplace during the Class Period concerning its results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause CorMedix to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of CorMedix within the meaning of §20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of CorMedix securities.

324. Each of the Individual Defendants, therefore, acted as a controlling person of CorMedix. By reason of their senior management positions and/or being directors of CorMedix, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, CorMedix to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control

over the general operations of CorMedix and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

325. By reason of the above conduct, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act for the violations committed by CorMedix.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, prays for relief and judgment against as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23, and certifying Plaintiff as the Class representative;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Plaintiff and other members of the Class such other and further relief as this Court may deem just and proper.

XI. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: April 22, 2024

Respectfully Submitted,

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff, by his attorneys, hereby certifies that to the best of his knowledge, the matter in controversy is not related to any other action. Plaintiff is not currently aware of any other party who should be joined in this action.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: April 22, 2024

Respectfully Submitted,

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